COMPARISON OF CONVENTIONAL AND REVERSE INSERTION TECHNIQUES OF I-GEL® IN OVERWEIGHT AND OBESE PATIENTS

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DR SONALI AHUJA

DEPARTMENT OF ANAESTHESIOLOGY
DAYANAND MEDICAL COLLEGE AND HOSPITAL
LUDHIANA, PUNJAB

DECLARATION BY THE CANDIDATE

I hereby declare that the thesis entitled "**COMPARISON OF CONVENTIONAL AND REVERSE INSERTION TECHNIQUES OF I-GEL® IN OVERWEIGHT AND OBESE PATIENTS**" submitted towards partial fulfillment of the requirements for the award of **MD in Anaesthesiology** degree to BFUHS is a compilation of original work carried out by me under the supervision of **Dr. Kamakshi Garg**, Professor, Department of Anaesthesiology, **Dr. Gurpreeti Kaur**, Associate Professor, Department of Anaesthesiology and **Dr. Anju Grewal**, Professor, Department of Anaesthesiology. No part of this thesis has formed the basis for the award of any degree previously.

_____

Dr. Sonali Ahuja
Department of Anaesthesiology,
Dayanand Medical College & Hospital,
Ludhiana, Punjab

Date:

Place:

CERTIFICATE OF SUPERVISORS

This is to certify that the work incorporated in this thesis entitled "**COMPARISON OF CONVENTIONAL AND REVERSE INSERTION TECHNIQUES OF I-GEL® IN OVERWEIGHT AND OBESE PATIENTS"** has been carried out by **Dr. Sonali Ahuja** under our direct supervision. The data incorporated in this thesis is original and genuine and has been carried out by the candidate himself.

Signature of Supervisor

Dr. Kamakshi Garg
Professor
Department of Anaesthesiology
DMC&H, Ludhiana

Signature of Co-Supervisors

Dr. Gurpreeti Kaur
Associate Professor
Department of Anaesthesiology
DMC&H, Ludhiana

Dr. Anju Grewal
Professor
Department of Anaesthesiology
DMC&H, Ludhiana

Date:

ENDORSEMENT BY THE HEAD OF THE INSTITUTE

This is to certify that the thesis entitled "**COMPARISON OF CONVENTIONAL AND REVERSE INSERTION TECHNIQUES OF I-GEL® IN OVERWEIGHT AND OBESE PATIENTS"** is a bonafide research work done by **Dr. Sonali Ahuja** under the supervision of **Dr. Kamakshi Garg**, Professor, Department of Anaesthesiology, **Dr. Gurpreeti Kaur**, Associate Professor, Department of Anaesthesiology and **Dr. Anju Grewal**, Professor, Department of Anaesthesiology and in this institution.

Principal

Dr. Sandeep Puri
Principal
DMC&H, Ludhiana

Date:

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Signature

Dr Sonali Ahuja
Department of Anaesthesiology,
Dayanand Medical College & Hospital,
Ludhiana, Punjab - 141001

Date:

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Dedicated

to

my Family,

friends

&

Teachers

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Dr. SONALI AHUJA

ABBREVIATIONS

ASA	American Society of Anaesthesiologists
BMI	Body mass index
cmH_2O	Centimetres of water
DBP	Diastolic blood pressure
ETT	Endo tracheal tube
$EtCO_2$	End tidal carbon di-oxide
ECG	Electrocardiography
hr	Hour
HR	Heart rate
i.e	That is
inj	Injection
iv	Intravenous
IQR	Inter quartile range
kg	Kilogram
LMA	Laryngeal mask airway
L	Litre
mg	Milligram
mcg	Microgram
min	Minute
mmHg	Millimetre of mercury
NIBP	Non invasive blood pressure
NRS	Numerical rating scale
OLP	Oral leak pressure
OR	Operating Room
PCV	Pressure controlled ventilation
Post op	Post operative
PACU	Post anaesthesia care unit
RR	Respiratory rate
SAD	Supraglottic airway device
SBP	Systolic blood pressure
SpO_2	Arterial oxyhemoglobin saturation
SD	Standard deviation
sec	Seconds
WHO	World Health Organisation
%	Percentage

ABSTRACT

Background: I-gel® has been used in obese patients for short to medium duration surgical procedures and has proved to be beneficial because of its high leak pressure. Insertion techniques have contributed to successful and appropriate placement of I-gel® in the first attempt, thereby avoiding multiple episodes of desaturation and other associated respiratory or haemodynamic complications. We hypothesized that the reverse technique of insertion would confer benefits in terms of better airway seal in obese patients in comparison to the conventional insertion technique.

Aim of Study: To compare the successful placement of I-gel® in the first attempt among two different techniques of insertion in overweight and obese patients as measured by an oral leak pressure.

Materials & methods: A prospective, randomized, interventional trial was conducted on 100 American Society of Anaesthesiologists I, II and III overweight and obese patients undergoing short surgical procedures under general anaesthesia, divided into 2 groups. In Group C, I-gel® was inserted with conventional technique while in Group R, I-gel® was inserted in the reverse manner. Successful placement of I-gel®, any manipulations required for successful placement, time taken for insertion, number of attempts for successful insertion, intra-operative and post-operative complications were studied. Data collected was statistically analysed.

Results: The mean Oral leak pressure (30.46 ± 3.76 versus 32.12 ± 3.10 mmHg, p-value 0.018) and the mean time of insertion (16.42 ± 1.86 versus 13.98 ± 1.97 sec, p-value 0.001) were statistically significant and favourable for Group R. No post operative complications were noted in any of the groups.

Conclusion: I-gel® insertion by reverse technique requires less time for its insertion than the conventional technique. There is better airway seal, easy insertion and fewer manipulations required in reverse technique as compared to conventional technique.

Keywords: Overweight, Obese, I-gel®, conventional, reverse, technique.

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INTRODUCTION

Airway management and oxygenation in obese patients can be challenging as obesity leads to a physiologically as well as in some occasions an anatomically difficult airway. Alterations in respiratory physiology include reduced functional residual capacity, increased oxygen consumption, reduced lung volumes, higher minute ventilation, reduced chest wall compliance and increased airway resistance. This predisposes them to multiple episodes of rapid desaturation during airway management especially during laryngoscopy and endotracheal intubation.[1,2]

Limited movement of atlantoaxial joint and cervical spine due to presence of fat pads, short thick neck, submental fat pad and increased amount of adipose tissue deposited in oral and pharyngeal spaces causing airway narrowing are predictors of an anatomically difficult airway in obese patients which makes it difficult to maintain a patent airway during mask ventilation and to perform direct laryngoscopy for endotracheal intubation.[1, 2] Although the association between obesity, difficult laryngoscopy and intubation is controversial but the presence of increased amount of pre-tracheal soft tissue and a greater neck circumference is a reliable predictor of difficult laryngoscopy and intubation.[3]

Endotracheal intubation is the preferred choice for securing the airway and for mechanical ventilation in obese patients as it provides a definitive airway after they lose their normal reflexes during general anaesthesia. Moreover the cuff of the tracheal tube is present inside the trachea which seals the laryngeal opening preventing aspiration of gastric contents. Higher inflation pressures can be achieved through an endotracheal tube to provide positive pressure ventilation.[4]

Although endotracheal intubation is considered gold standard to secure airway in obese patients; the difficult laryngoscopy and intubation results in increased haemodynamic stress response. In addition there have been reports of higher incidence of hoarseness, sore throat, dysphagia, etc due to multiple attempts at endotracheal intubation.[4-6]

As an alternative to endotracheal intubation, a second generation supraglottic airway device (SAD) has proved beneficial in obese patients because of its easy insertion coupled with higher rates of first attempt successful insertion,[4-6] which facilitates in reducing the episodes of rapid desaturation with concomitant lesser stimulation of laryngeal reflexes. Trials comparing endotracheal intubation and SAD insertion have amply demonstrated lower incidence of sore throat, dysphagia and haemodynamic changes with use of latter.[4, 7] Muscle relaxation is not necessary for the insertion of SAD and this helps in preventing atelectasis caused by muscle relaxation required during endotracheal intubation thus providing better post operative lung functions.[7] However the use of muscle relaxants facilitates the insertion of SAD by relaxing the jaw. Additionally the second generation laryngeal mask airway has been observed to be associated with high leak pressures facilitating mechanical ventilation.[5,6 8,9] They have been routinely used as primary airway device, for emergency airway management, as a backup to failed intubation and as conduits for tracheal intubation.

The supraglottic airway devices are associated with the risk of aspiration, inadequate insertion, suboptimal ventilation, bronchospasm, laryngospasm etc.[10] The presence of gastric drain tube in second generation SAD provides protection against aspiration by providing a separate channel for efflux of gastric contents, [4] hence they can be used for short surgical procedures provided the device is placed successfully.[7,10]

Among various second generation SADs, I-gel® is a relatively new, single use device. It has a pliable gel like cuff made of thermoelastic material (styrene ethylene butadyiene styrene) which adjusts to the patient's supraglottic anatomy and provides a non inflatable seal. [11, 12] The presence of separate gastric channel diminishes the risk of regurgitation and aspiration. [11] It has an epiglottic ridge which rests on the base of tongue and resists upward and outward movement of the device. It is easier to train non-anaesthesiologists to correctly place the device making it useful for emergency situations.[11,12] It has also been

proved successful in lateral and prone positions apart from the supine position.[13]

There are various studies comparing I-gel® with other SADs in lean patients and they show that I-gel® can be used with higher ventilation pressures than other SADs due to its better anatomical seal.[14,15] It provides high leak pressure comparable to other SADs and has easier and faster insertion.[16-18] I-gel® has been used in obese patients for short to medium duration surgical procedures and has been proved to be beneficial because of its high leak pressure in conjunction with easier positioning and faster insertion.[19] It can also be used as conduit for fibreoptic bronchoscopy and guide for intubation in case we require a definitive airway after the surgery.[13]

Improper placement of SADs increases the risk of aspiration. The failed placement of the device is generally due to the bulky tongue or tongue folding which obstructs the advancement of cuff further into the pharynx.[20,21] Studies have compared different techniques of insertion in terms of faster and easier placement of the device.[20-23]

Insertion technique contributes to successful and appropriate placement of I-gel® in the first attempt, thereby avoiding multiple attempts which not only causes trauma to the oral cavity but also increase the time to secure the airway causing episodes of desaturation and other associated respiratory or haemodynamic complications[21,23] which is very important for obese patients owing to shorter safe apnea time.

The standard conventional technique which entails placement of I-gel® with concavity facing the mandible in a pen-holding manner and inserting the device till it fits over the larynx, has been evaluated by multiple investigators in lean patients. They observed successful placement at the first attempt in majority of their patients.[21-23]

Reverse technique in which I-gel® is inserted into the oral cavity with concavity of the device facing the hard palate and rotated 180° on reaching the oro-pharynx and then further into the laryngo-pharynx till it fits over the larynx, has been studied by various authors in non-obese individuals.[21,23] They observed higher rates of successful placement

than the conventional technique in terms of success at first attempt and time taken for appearance of a square wave end-tidal carbon di-oxide waveform. They also reported better seal leading to higher leak pressures.[21,23]

We hypothesized that the reverse technique of insertion would confer benefits in terms of better airway seal in obese patients in comparison to the conventional insertion technique. Since we could not elucidate scientific studies comparing conventional versus reverse techniques of I-gel® insertion in obese patients, hence we proposed to comparatively evaluate both of these insertion techniques of I-gel® in overweight and obese patients, in terms of successful placement at first attempt, Oral Leak Pressures (OLP), manipulations during insertion, episodes of intra-operative desaturation and post-operative complications if any.

AIMS AND OBJECTIVES

To compare the successful placement of I-gel® in the first attempt among two different techniques of insertion in overweight and obese patients as measured by an Oral Leak Pressure.

REVIEW OF LITERATURE

Obesity is usually associated with difficult airway, difficult bag mask ventilation, difficult laryngoscopy, difficult endotracheal intubation, difficult tracheostomy and an added risk of aspiration.[3]

Obese patients have short thick neck, restricted neck movements and more perilaryngeal soft tissue therefore it is difficult to get the oral, pharyngeal and laryngeal inlet in line for endotracheal intubation. Apart from the anatomically difficult airway, they also have a physiologically difficult airway which includes reduced functional residual capacity, increased oxygen consumption, reduced lung volumes higher minute ventilation, reduced chest wall compliance and increased airway resistance.[1-4] This predisposes them to multiple episodes of desaturation during airway management especially during laryngoscopy and endotracheal intubation.[3]

They usually have concomitant co-morbidities like diabetes mellitus, hypertension, obstructive sleep apnoea, chronic obstructive pulmonary disease, gastro-oesophageal reflux disease, etc which further predisposes them to physiologically and anatomically difficult airway.[1,2]

Endotracheal intubation is the preferred choice for securing the airway and for mechanical ventilation during general anaesthesia in obese patients.[4] Furthermore the difficult laryngoscopy and intubation in obese patient results in increased haemodynamic stress response. [3-5]

In addition there have been reports of higher incidence of hoarseness, sore throat, dysphagia etc due to multiple attempts at endotracheal intubation.[4-5]

As an alternative to endotracheal intubation, a second generation supraglottic airway device (SAD) has proved beneficial in obese patients because of the easy insertion coupled with higher rates of successful insertion at first attempt.[3-7] Several investigators have compared endotracheal intubation with SADs using parameters like leak pressure, ease of insertion and urgency to secure airway. They

concluded that SADs can be used as an alternative to endotracheal intubation.[3-7]

Murphy C et al in a review stated that airway management and oxygenation in obese patients is challenging. These challenges in oxygenation and ventilation may persist throughout the perioperative period. They suggested that newer generation double lumen supraglottic airway devices provide higher leak pressures and may be considered safe in obese patients. They can also provide a conduit for bronchoscopic intubation. Although second generation SADs are safer in obese patients but there are risks of aspiration hence caution should be exercised while using these devices in morbidly obese individuals.[3]

Cochrane systematic review comparing studies on use of Proseal LMA and Endotracheal tube (ETT) in obese patients concluded that, though Proseal LMA takes more time to insert than ETT and a failure rate of 3-5% can be anticipated in obese patients, but once properly fitted it provides equally good ventilation as compared to endotracheal intubation. They found significant improvement in oxygenation during and after the surgery and reduced post-operative complications like coughing, sore throat, hoarseness, etc with the use of Proseal LMA.[4]

Zoremba M et al recruited 162 patients posted for short to medium duration surgeries of 40-120 minutes and compared intubation and Proseal LMA in moderately obese adults. They included the data of 134 patients after accounting for dropouts and aimed to evaluate the influence of airway management i.e intubation versus LMA on postoperative lung volumes and arterial oxygen saturation in early post-operative period. They concluded that the use of LMA during minor peripheral surgery confers advantages for moderately obese adults in terms of early recovery of post-operative lung functions and may be considered as an alternative to endotracheal intubation for moderately obese patients undergoing short surgeries.[7]

Uppal V et al compared I-gel® with cuffed endotracheal tube during pressure controlled ventilation (PCV) in 20 patients (BMI <35 kg/m^2). They found that there was no significant difference in the leak fractions between the two groups at 15-20 cm H_2O. There was no evidence of

gastric insufflations with I-gel® at any of the pressures used during PCV. Hence I-gel® can be used as a reasonable alternative to tracheal tube during PCV with moderate airway pressures.[12]

Lai CJ et al compared I-gel® with ETT in 40 non-obese patients undergoing laproscopic pneumoperitoneum surgeries. They evaluated the respiratory parameters in supine and trendlenberg position and found no difference in the leak fraction between I-gel® and ETT group (6.20% vs 6.38% respectively), (p=0.883). They concluded that I-gel® provides a suitable alternative to ETT when used in laproscopic pneumoperitoneum and trendlenberg positioning. The I-gel® group produced similar leak fractions, leak volumes and airway pressure as in the ETT group. In addition, the I-gel® group had significantly lower resistance and higher compliance compared with the ETT group. They proposed that the difference can be because of the lower internal diameter of I-gel® as compared to ETT.[24]

SADs can be used to secure airway in elective as well as emergency situations and are proved beneficial even when dealing with obese patients.[10] Solanki et al compared actual and ideal body weight for selection of appropriate size of Proseal LMA in 124 overweight and obese patients and concluded that ideal body weight is preferable for the size selection when compared to actual body weight in overweight and obese patients as the smaller size cuff provides better sealing and less trauma than the larger sized cuff due to the presence of smaller upper airway in obese patients.[25]

The different types of LMA have been studied and compared so far. Second generation LMA have a gastric outlet to prevent gastric insufflation. In a randomised trial on comparative evaluation of ProSeal LMA (P), I-gel® (I) and Supreme LMA (S) in 84 adult patients undergoing elective surgery by Singh A et al showed that the OLP was more with P than I and S but I-gel® was easier to insert and less time consuming. The OLP of I-gel® increased towards the end of the surgery due to its thermoelastic hood which expands due to body temperature. [9] This high OLP is advantageous for our study as it

would provide better seal and hence lesser chances of oesophageal reflux.

Uppal V et al in 2009 studied randomized crossover comparison between the performance of I-gel® and LMA-Unique in 39 anaesthetized, paralysed non-obese adults and found that there were no significant differences between the airway leak pressures and success rate of first time insertion of the two devices. The number of manipulations required after insertion to achieve a definitive airway was similar in both the groups. They concluded that I-gel® is a reasonable alternative to LMA-Unique for volume controlled ventilation during anaesthesia; also it has a lower insertion time.[11]

Maitra S et al studied meta-analysis of Proseal and I-gel® in adult patients under general anaesthesia and they concluded that though I-gel® was easier to insert but the time to insert the device, first insertion success rates and ease of insertion were similar for both the device, also Proseal provided higher seal pressure than I-gel®.[18]

Kara D et al compared Baska and I-gel® in 200 patients undergoing urological procedures under general anaesthesia of less than 2 hours duration. They compared the two devices in terms of time of insertion, number of attempts, postoperative complications and laryngopharyngeal morbidity scores. They concluded that though the devices were similar in most aspects but I-gel® required less time for its insertion as compared to Baska.[16] Theiler et al compared pediatric sized I-gel® with Ambu auraonce in anesthetized and ventilated children scheduled for elective day care surgery under general anaesthesia. The primary outcome was OLP and other outcomes were first attempt overall success, time to sufficient ventilation and adverse events. They concluded that I-gel® showed significantly higher leak pressures than Ambu auraonce and there were no major side effects in any of the groups.[26]

Various studies have shown advantages of I-gel® over other LMAs. I-gel® was invented by Muhammed Nassir in 2003 and developed by Intersurgical in Berkshire, UK, [27] has a non-inflatable gel like cuff made up of thermoelastic material and a buccal stabilizer to prevent

malpositioning. It fits with the patient's perilaryngeal anatomy and provides a reliable seal.[13, 14] It is easier to insert and has high success rates of insertion at first attempt. It can be used as a rescue device to secure airway in emergency conditions. The size of I-gel® to be inserted is based on manufacturer's guidelines (30-60 kg - size 3, 50-90 kg - size 4, >90 kg - size 5).

Oral Leak Pressure (OLP) is an important parameter deciding proper placement of the LMA, especially in obese patients where risk of aspiration is more if the device is not fitted properly.

There are many methods to check Oral Leak Pressure. In a study by Keller C et al four methods were suggested for assessing airway sealing pressure with LMA in adults. Test (1) audible noise: involved detection of an audible noise by listening over the mouth. Test (2) oral capnography: involved placing a carbon di-oxide sampling line 5cm inside the mouth alongside the LMA tube and noting when CO_2 was first seen above baseline on the monitor screen. Test (3) manometric stability: involved observation of an anaeroid manometer dial as the pressure from the breathing system increased, and noting the airway pressure at which the leak was in equilibrium with fresh gas flow. Test (4) auscultation: involved detection of an audible noise using a stethoscope placed just lateral to thyroid cartilage. They concluded that all of these tests for assessing OLP were excellent.[28]

A study by Weber U et al compared I-gel® and LMA-Unique in 50 patients in terms of leak pressure, ease of insertion, time and number of attempts of insertion in mild to moderately obese patients (BMI >25 and <35 kg/m²) posted for elective short-term surgeries. They observed slightly lower scores for difficulty of insertion with LMA-Unique and statistically significant shorter insertion time with I-gel®. They observed that I-gel® can be used with higher ventilatory pressures than LMA-Unique. Hence I-gel® is a safe and effective alternative supraglottic airway device in patients with mild to moderate obesity with mouth opening < 4cm. [15]

Laryngeal mask airway can also be inserted without the use of muscle relaxant but in obese patients muscle relaxant helps in decreasing the

tone of laryngeal and pharyngeal muscles. It aids in easy and less traumatic insertion of the device by providing a relaxed jaw, sufficient mouth opening along with the suppression of airway reflexes thus facilitates placement of LMA.[29,30]

In a study by Krishnappa S et al to assess whether loss of motor response to jaw thrust can be a reliable clinical indicator of anaesthetic depth for LMA insertion. They used propofol in titrated doses till the loss of motor response to jaw thrust in one group and fixed dose in the other. They found that loss of motor response to jaw thrust is reliable and favourable indicator for insertion of LMA classic.[31]

Prabha R et al compared I-gel® for general anaesthesia in obese and non-obese patients. A total of 32 patients were studied and results showed a higher mean OLP for obese patients than non-obese. The use of muscle relaxants decreased the tone of laryngeal and pharyngeal muscles and reduced the OLP of SAD. Excess perilaryngeal tissue in obese patients may lead to better seal between the cuff of I-gel® and laryngeal inlet. They concluded that I-gel® is as effective in obese patients as in non-obese patients when used for securing the airway for surgical procedures.[19]

Nasseri K et al studied effect of low dose atracurium on LMA insertion They found that jaw relaxation and ease of LMA insertion in the study group is significantly better than the control group (without the use of relaxant). Average time needed for insertion was also significantly lower in the study group. Haemodynamic response was similar in both groups and post-operative complications like sore throat were more in control group. They concluded that using low dose atracurium decreases the time taken for LMA insertion, it increases the jaw relaxation and facilitates the placement of LMA.[30]

Technique of insertion is an important indicator for successful placement of the device. Various techniques of insertion like conventional and reverse technique to aid for easy insertion and better success rate at first attempt have been tried by different authors. The standard conventional technique which entails placement of I-gel® with concavity facing the mandible in a pen-holding manner and inserting

the device till it fits over the larynx, has been evaluated by a few investigators in obese patients. They observed successful placement at the first attempt in majority of their patients.[21-23] The reverse technique in which I-gel® is inserted into the oral cavity with concavity of the device facing the hard palate and rotated 180° on reaching the oro-pharynx and then further into the laryngo-pharynx till it fits over the larynx, has been studied by various investigators in non-obese individuals. [21,23] They observed higher rates of successful placement with reverse technique than the conventional technique in terms of success at first attempt and time taken for appearance of a square wave end-tidal carbon di-oxide waveform. They also reported better seal leading to higher leak pressures with reverse technique. [21,23]

In a study conducted by Sharda M et al reverse technique of insertion of LMA I-gel® was evaluated in 100 ASA I and II patients. They found that mean time required for I-gel® insertion in reverse technique was statistically significantly less when compared with conventional technique (17.5± 6.9 and 20.8± 5.9sec respectively). The success rate of first attempt with reverse technique was also better than conventional technique but it was statistically insignificant. Placement time was long in some patients with smaller mouth openings. The study concluded that reverse technique is associated with easier insertion and lesser placement time than that with the conventional technique. The fit of LMA was similar in both groups with the leak volumes (inspired-expired tidal volumes) being similar.[21]

In another study conducted by Bhardwaj et al one hundred and thirty five patients were recruited between 18-50 years of age and ASA I, II undergoing elective surgeries under general anaesthesia. They compared three insertion techniques of I-gel® placement i.e standard (conventional), reverse and rotational. The mean time of insertion was 18.04±5.65 sec for conventional technique and 15.00±5.72 sec for reverse technique, the overall success rate was 91.1% and 95.6% for the two groups respectively. They concluded that all the techniques of insertion of I-gel® are equally good and the choice of technique depends on the comfort and experience of the anaesthesiologist

inserting the device. [23] Sen I et al in a case study of a 30 yr old woman posted for hysteroscopic dilatation and curettage demonstrated reverse insertion technique of I-gel®. They concluded that the reverse technique was easy to use, atraumatic and could be used for I-gel® insertion if first attempt by classic technique fails.[32]

Reverse technique of LMA insertion has also been studied in paediatric age group patients. Soh et al studied the use of standard and re-inforced type of LMA in 67 paediatric patients undergoing general anaesthesia and compared them using reverse and standard technique. Fifteen seconds were allowed for each attempt. A blinded observer was asked to assess the final position of LMA using a fibreoptic bronchoscope. The success rate using standard technique was 90.3% while it was 100% using reverse technique; (p=0.06). It showed that reverse technique can be used as an acceptable alternative to the standard technique.[33]

Azad AK modified the reverse technique with triple airway manoeuvre for placing LMA among 100 children of 2 to 7 years of age. They compared Brain's technique with traditional sniffing manoeuvre in classical group and partially inflated LMA was placed by blending reverse rotational technique by triple airway manoeuvre in the reverse rotational group. They found that the triple airway manoeuvre maximized the success rate of insertion at first attempt and minimized the rate of complications when compared to that of the conventional technique.[34] Brimacombe et al studied the insertion of LMA classic, with cuff deflated, partially inflated and fully inflated with standard technique and reverse technique of insertion. The study was conducted on 120 ASA I and II non-obese patients. The vocal cord position was graded using a fibreoptic bronchoscope. Laryngospasm, transient glottis closure and presence of blood was also noted. They found that standard technique with deflated cuff and reverse technique were better than other two techniques.[35]

Kim HC et al studied rotational and conventional technique of I-gel® in 184 non-obese patients and concluded that the rotational group had several advantages over the standard technique such as shorter

insertion time, better airway seal and fewer post operative complications. There was least resistance by the tongue and thus easy insertion of I-gel® by rotational technique.[22]

Koo B et al also studied the same techniques using LMA flexible and found comparable results between the two groups in terms of success rate at first attempt, insertion time, manipulations required for insertion, haemodynamic variables and complications.[36] They concluded that on comparing rotational and conventional technique it was found that the rotational technique is better than conventional in terms of less resistance by the tongue, less time taken for the insertion of the device and a better or atleast a comparable success rate at first attempt.

After thorough search of the available literature, we planned to further investigate the role of conventional and reverse techniques of insertion of I-gel® in overweight and obese patients and to comparatively evaluate them which would help us choose the better technique of insertion with respect to successful placement, ease and time of insertion.

MATERIALS AND METHODS

SOURCE OF DATA

The study was conducted in Department of Anaesthesiology, Dayanand Medical College and Hospital, Ludhiana after approval from the hospital ethics committee. A written informed consent was obtained from all the patients selected for study.

METHOD OF COLLECTION OF DATA

A prospective, randomised, interventional study was conducted on 100 ASA I, II and III adults with BMI ≥23 kg/m² and ≤40 kg/m², as per Asian criteria of BMI for nutritional status.[37-40] Hence we included overweight, obese class I and obese class II patients as per this criterion in our study.[37-40] A total of 100 patients were recruited for the study to account for 10% possibility of drop-outs and an equal number was randomised using computer generated random numbers contained in sealed, sequentially numbered envelopes, which were opened by an independent anaesthesiologist not involved in the study.

Inclusion criteria: Elective surgical procedures lasting upto 120 min, surgeries in supine position, adults of both sex, BMI ≥23 kg/m² and ≤40kg/m², age ≥18yrs and ≤60yrs.

Exclusion criteria: Patients with known or predicted difficult airway, mouth opening < 2.5 cm, surgeries in prone or lateral position, BMI <23 kg/m² and >40 kg/m², ASA IV patients, pathology of the neck or upper respiratory tract, abnormal head, airway or neck anatomy like recent radiotherapy, recent oral surgery, any oral or pharyngeal growth, presence of any significant acute or chronic lung disease, emergency surgeries, thoracic surgeries, neuro-surgeries, cardiac surgeries and airway surgeries, cervical spine injury, any mass compressing over the neck, pregnancy and refusal to participate, were excluded.

Group Allocation - A written informed consent was obtained from all the patients. Patients were divided into 2 groups of 50 patients each.

Group (C): I-gel® was inserted by conventional technique with concavity facing the mandible in a pen-holding manner and inserting the device till it fits over the larynx (Brain's technique).

Group (R): I-gel® was inserted into the oral cavity with concavity of the device facing the hard palate and on reaching the oropharynx the device was rotated 180° and then further into the laryngopharynx till it fits over the larynx (like Guedel's airway).

Anaesthesia technique - All patients were subjected to routine pre-operative assessment and standard fasting protocols.

In the operating room (OR), all patients were positioned in RAMP position and pulse oximeter, non invasive blood pressure (NIBP), end tidal CO_2 ($EtCO_2$), 5 lead electrocardiography (ECG) monitors were attached and baseline values were recorded from the mean of three values after positioning and settling of patient on OR table. Intravenous access was secured and intravenous injections of midazolam 0.05 mg/kg and metoclopramide 10 mg were administered.

After pre-oxygenating the patient with 100% oxygen for 3-5 minutes with a tight fitting appropriate size anatomical face mask, anaesthesia was induced with intravenous injections of fentanyl 2 mcg/kg and 1% propofol 2-2.5 mg/kg titrated to loss of verbal response. Neuromuscular blockade was achieved by intravenous injection of atracurium 0.5 mg/kg. After achieving adequate jaw relaxation i.e. loss of motor response to jaw thrust, airway was secured by an appropriate size I-gel®.

I-gel® size was selected based on patient's weight as per manufacturer's guidelines (30-60 kg - size 3, 50-90 kg - size 4, >90 kg - size 5). The front, sides and back of the I-gel® cuff was lubricated with a water based jelly before insertion.

Insertion of the airway devices was performed by an anaesthesiologist with an experience of ≥ 100 LMA insertions and ≥ 50 I-gel® insertions using either technic as per random number allocation.[15] A nasogastric tube of appropriate size was passed through the gastric tube channel in all the cases.

The lungs were mechanically ventilated using volume controlled ventilation delivered by an anaesthesia work station (Drager Fabius Plus) set to deliver a tidal volume of 8ml/kg, respiratory rate to maintain

EtCO2 between 30 and 40 mmHg, inspiratory and expiratory ratio of 1:2 and a peak end-expiratory pressure of 5 cm of water.

The total fresh gas flow was maintained at 1.5 L/min. Anaesthesia was maintained by desflurane 4-6% in 50:50 Oxygen and nitrous oxide. Additional fentanyl 1mcg/kg i.v. was given when clinically needed during anaesthesia.

At the end of the procedure neuromuscular blockade was reversed using intravenous injections of neostigmine 0.04 mg/kg and glycopyrrolate 0.001 mg/kg and I-gel® was removed after confirming the return of spontaneous and normal pattern of ventilation and sustained head lift for atleast 5 seconds. Sustained hand-grip, leg-lift or eye opening have been demonstrated to have a low sensitivity in predicting recovery of neuromuscular function.[41] Patients were then shifted to post-anaesthesia care unit for observation.

Observations:

PRIMARY OUTCOME

Successful placement at first attempt - Successful placement of the I-gel® was confirmed by gently squeezing the reservoir bag and observing visible chest rise, bilateral chest auscultation, appearance of a square wave end-tidal carbon dioxide waveform [21], by checking Oral Leak Pressure (OLP) and peak airway pressure of ≥10mmHg during manual controlled ventilation. [22]

To perform the OLP, the fresh gas flow was adjusted to 3L/min, and the adjustable pressure limiting valve of the circle system was completely closed. With no peak end expiratory pressure, the minimum airway pressure was measured at which audible gas leak occured as heard using a stethoscope placed just lateral to the thyroid cartilage. Airway pressures were not allowed to exceed 40cmH_2O. [15,19]

SECONDARY OUTCOMES

Manipulations done during insertion - Any manipulations done during insertion of the I-gel® were noted down like gentle withdrawal with advancement of the I-gel®, chin lift, jaw thrust, head extension, neck flexion or change of size. [19]

Number of attempts and Failed placement - Number of attempts needed for successful placement were recorded. A maximum of three attempts were allowed with each device. Any change in size of device was also considered as an attempt.[9]

If after three attempts of I-gel® placement, the criteria for successful placement of I-gel® were not met with, it was considered as failed placement. Need for the change of type of airway device was also considered as failed placement.[19]

Insertion time of I-gel® - The insertion time was defined as the time from picking up the device until the initiation of mechanical ventilation and appearance of square wave capnograph. [15] Maximum time allowed for each attempt was 60 sec.[22]

Difficulty of insertion - The difficulty of insertion as graded by the anaesthesiologist inserting the device which was graded as easy=1, moderate=2, difficult=3 and impossible=4. [15]

Haemodynamic parameters – HR, ECG rhythm, NIBP, SpO_2 and $EtCO_2$ were recorded at 1 minute intervals from starting the induction till the successful placement of the device was confirmed and then once after placement of the device, after removal of the device and after shifting the patient to post anaesthesia care unit.

Complications – Staining with blood was observed on the I-gel® at the time of removal towards the end of the surgery. [15]

Number of episodes of desaturation i.e., SpO_2 < 90% were noted down, [7] the patients were mask ventilated with 100% oxygen till optimal SpO_2 level was reached (95%) and this time of ventilation was included in effective airway time. [9]

Dental injury if any was noted down. [4]

Patients were followed up for 12 hours after the surgery for any complaints of sore throat, dysphagia and dysphonia.

Sore throat was rated on Numerical Rating Scale (NRS 0-10) by asking the patient verbally about the intensity of throat pain, (0- no pain, 1-3- mild pain, 4-6- moderate pain, 7-10- severe pain) during the follow up

in post anaesthesia care unit. A score of more than 4 on NRS was considered as sore throat. [36]

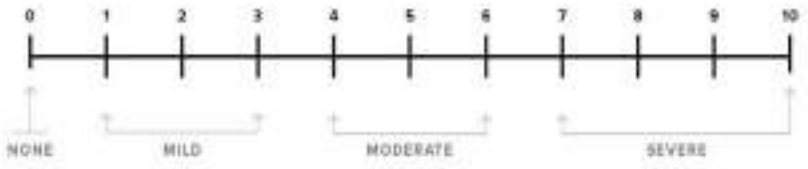

Figure 1 Numeric Pain Rating Scale

Statistical Analysis

Data was described in terms of range; median (inter quartile range IQR), mean ± standard deviation (± SD), frequencies (number of cases) and relative frequencies (percentages) as appropriate. Comparison of quantitative variables between the study groups were done using ANOVA. For comparing categorical data, Chi square ($\chi 2$) test was performed and Fischer exact test was used when the expected frequency was less than 5. A probability value (p value) less than 0.05 was considered statistically significant. All statistical calculations were done using SPSS (Statistical Package for the Social Science) SPSS 21 version statistical program for Microsoft Windows.

Sample size calculation:

Sample size calculation was based on the data from previous study, [19] which compared OLP values in obese vs non-obese patients with the use of I-gel®. The mean OLP reported was 27.38 ± 4.38 cmH_2O in the obese group.

Hence a sample size of 50 patients in each group was proposed to detect a clinically important difference of 3 cmH_2O with a standard deviation of 5 cmH_2O in OLP. This proposed sample size was calculated with an alpha error of 0.05, a power of 80% and an estimated dropout rate of 10%.

OBSERVATIONS AND RESULTS

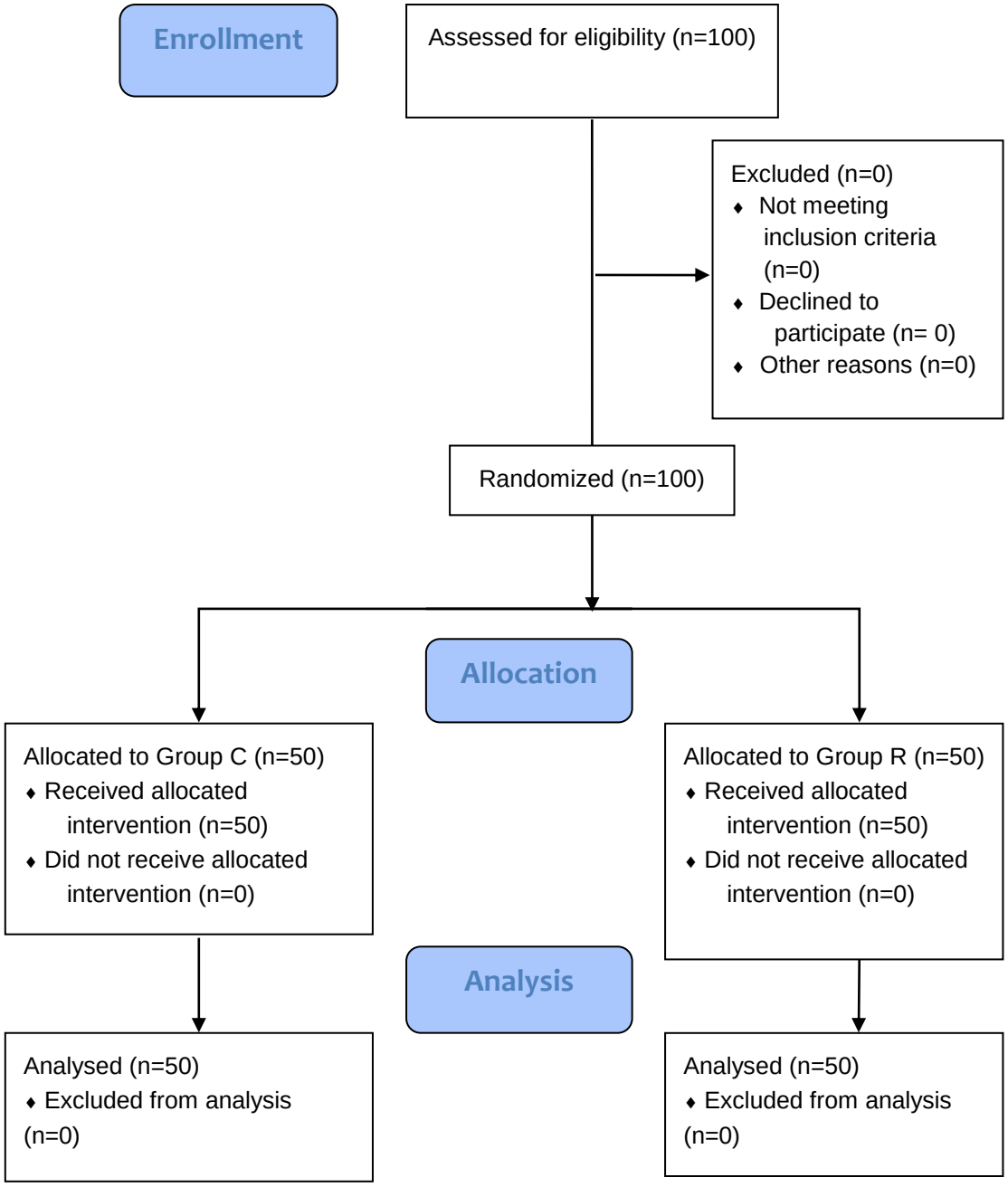

Figure 2 Consort flow Diagram of the study

A total of 100 patients were enrolled for the study and all of them completed the study. They were divided in 2 groups of 50 patients each and were randomly allocated to either of the groups by computer generated random numbers. All of them received the interventions and there were no dropouts. They were analysed using SPSS 21 version statistical program for Microsoft Windows.

Table 1: Distribution of patients according to gender.

		Group C		Group R		Total	Chi-square value	p-value
		No. of cases	%	No. of cases	%			
Gender	Female	35	70%	42	84%	77	2.767	0.153
	Male	15	30%	8	16%	23		
Total		50	100%	50	100%	100		

The two groups were comparable with respect to gender; however there were more of female patients as compared to male in both the groups. In Group C there were 70% females and 30% males and in Group R there were 84% females and 16% males.

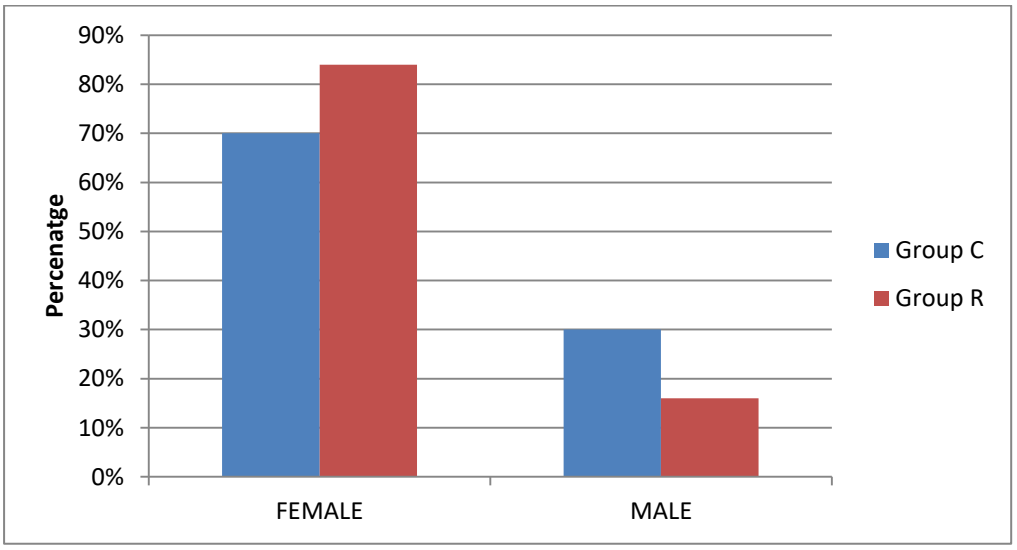

Figure 3: Distribution of patients according to gender.

Table 2: Distribution of patients according to age (years).

	Group C		Group R		t	p-value
	Mean	SD	Mean	SD		
Age (years)	40.56	±14.16	38.16	±11.77	0.922	0.359

Both the groups were comparable with respect to age, mean age in Group C was 40.56 ± 14.16 years and that of Group R was 38.16 ± 11.77 years.

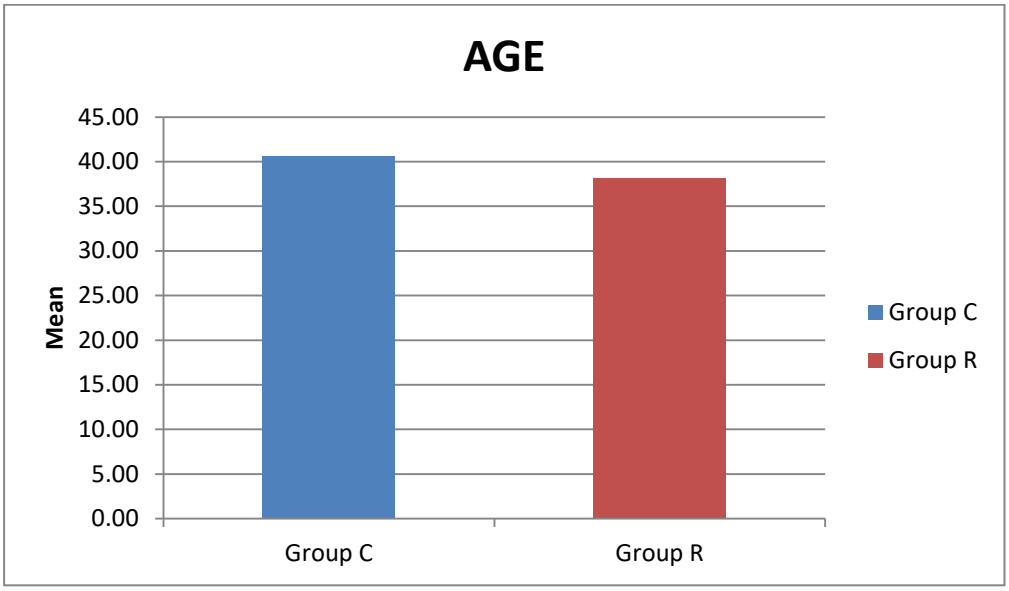

Figure 4: Distribution of patients according to age (years).

Table 3: Distribution of patients according to height (cm), weight (kg) and Body mass index (kg/m²).

	Group C		Group R		t	p-value
	Mean	SD	Mean	SD		
Height (cm)	160.94	±7.81	159.30	±6.33	1.153	0.252
Weight (kg)	73.64	±14.92	71.36	±11.64	0.852	0.396
BMI (kg/m²)	28.39	±4.44	28.14	±4.05	0.294	0.769

Both the groups were comparable with respect to height (cm), weight (kg) and BMI (kg/m²). The mean height of Group C was 160.94 ± 7.81 cm and of Group R was 159.30 ± 6.33 cm. Similarly, mean weight of Group C was 73.64 ± 14.92 kg and in Group R was 71.36 ± 11.64 kg and mean BMI of Group C was 28.39 ± 4.44 kg/m² and in Group R was 28.14 ± 4.05 kg/m².

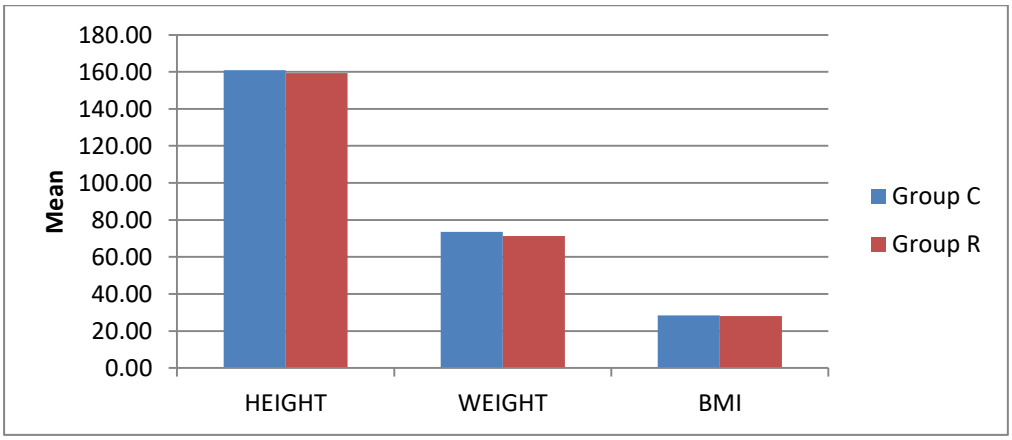

Figure 5: Distribution of patients according to height (cm), weight (kg) and Body mass index (kg/m²).

Table 4: Distribution of patients according to weight classification by BMI in adult Asians [37].

		Group C		Group R		Total	Chi-square value	p-value
		No. Of cases	%	No. Of cases	%			
Classification	Overweight	16	32%	13	26%	29	1.076	0.584
	Obese I	17	34%	22	44%	39		
	Obese II	17	34%	15	30%	32		
Total		50	100%	50	100%	100		

The two groups were comparable in terms of classification of BMI in adult Asians with Group C comprising of 32% overweight, 34% obese 1 and 34% obese 2 patients and Group R comprising of 26% overweight, 44% obese 1 and 30% obese 2 patients.

Figure 6: Distribution of patients according to weight classification by BMI in adult Asians [37].

Table 5: Distribution of patients according to American Society of Anaesthesiologists Grading.

		Group C		Group R		Total	Chi-square value	p-value
		No. of cases	%	No. of cases	%			
ASA Grading	1	22	44%	26	52%	48	2.155	0.341
	2	24	48%	23	46%	47		
	3	4	8%	1	2%	5		
Total		50	100%	50	100%	100		

The two groups were comparable in terms of ASA Grading.

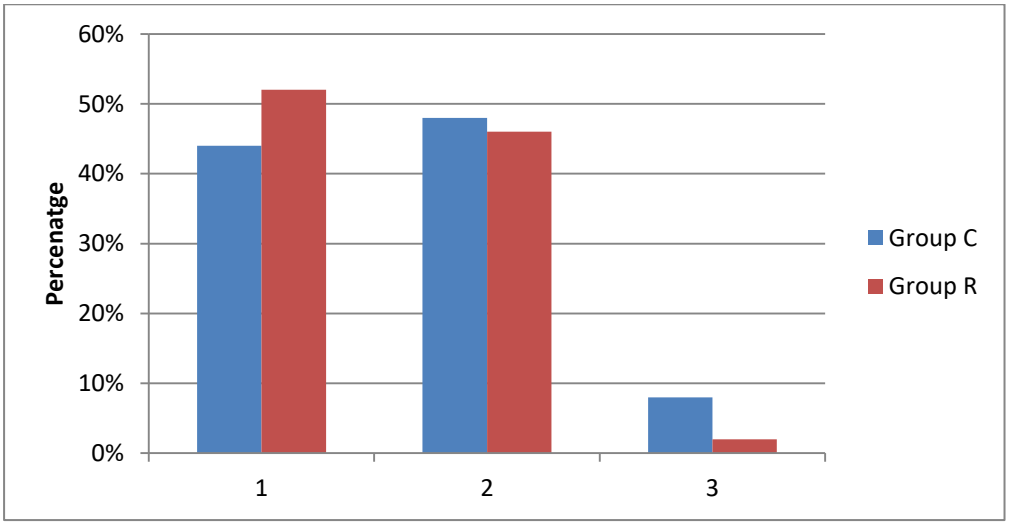

Figure 7: Distribution of patients according to American Society of Anaesthesiologists Grading.

Table 6: Distribution of patients according to mean duration of surgery (min).

	Group C		Group R		t	p-value
	Mean	SD	Mean	SD		
Duration (min)	51.90	±18.62	53.40	±24.69	-0.343	0.732

The two groups were comparable in terms of duration of surgery with mean duration of surgery for Group C being 51.90 ± 18.62 min and in Group R being 53.40 ± 24.69min.

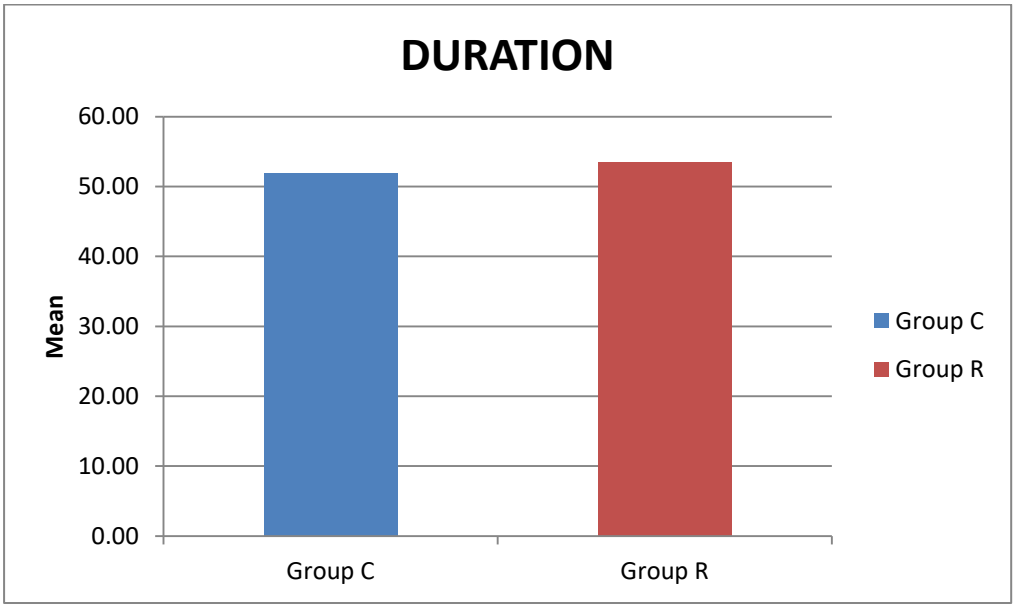

Figure 8: Distribution of patients according to mean duration of surgery (min).

Table 7 : Distribution of patients in terms of airway physical assessment.

		Group C		Group R		Total	Chi-square value	p-value
		No. Of cases	%	No. Of cases	%			
Dentition	Edentulous	2	4%	2	4%	4	2.700	0.259
	Full	43	86%	37	74%	80		
	Partial	5	10%	11	22%	16		
Buck teeth	Cannot prognath teeth	1	2%	0	0%	99	1.010	0.315
	Can prognath teeth	49	98%	50	100%	1		
Mouth opening (cm)	4	1	2%	0	0%	1	3.512	0.622
	4.5	9	18%	12	24%	21		
	5	12	24%	12	24%	24		
	5.5	16	32%	17	34%	33		
	6	10	20%	9	18%	19		
	6.5	2	4%	0	0%	2		
Thyromental distance (cm)	> 6.5	50	100%	50	100%	100		
Neck movement	Normal	48	96%	50	100%	98	2.041	0.153
	Restricted to extension	2	4%	0	0%	2		
TMJ mobility	Normal	50	100%	50	100%	100		
Upper Lip Bite test	I	24	48%	25	50%	49	0.041	0.980
	II	25	50%	24	48%	49		
	III	1	2%	1	2%	2		
Abnormal head and neck anatomy	No	50	100%	50	100%	100		

The two groups were comparable in terms of airway physical assessment.

Table 8: Distribution of patients according to the size of I-gel® inserted.

		Group C		Group R		Total	Chi-square value	p-value
		No. of cases	%	No. of cases	%			
Size of I-gel®	3	8	16%	13	26%	21	2.349	0.309
	4	33	66%	32	64%	65		
	5	9	18%	5	10%	14		
Total		50	100%	50	100%	100		

The size of I-gel® used in both the groups was comparable. The most commonly used size of I-gel® in both the groups was size 4.

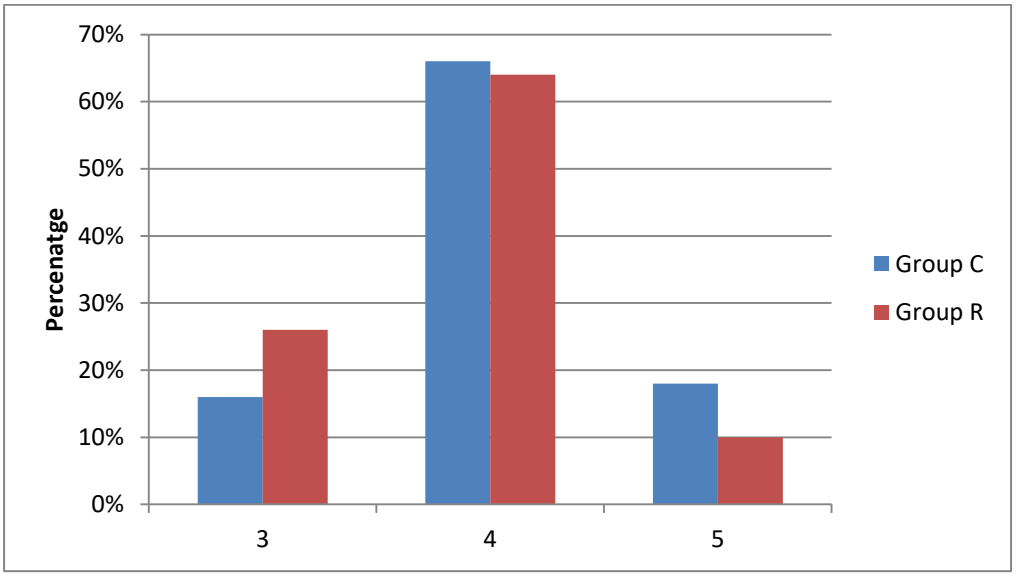

Figure 9: Distribution of patients according to the size of I-gel® inserted.

Table 9: Distribution of patients according to mean time of successful insertion of I-gel® in the two groups.

	Group C		Group R		t	p-value
	Mean	SD	Mean	SD		
Time (sec)	16.42	±1.86	13.98	±1.97	6.355	0.001

The mean time of insertion of Group C was 16.42 ± 1.86 seconds and that of Group R was 13.98 ± 1.97 seconds. The difference in mean time of successful insertion of I-gel® among the groups was found to be statistically significant (p-value 0.001).

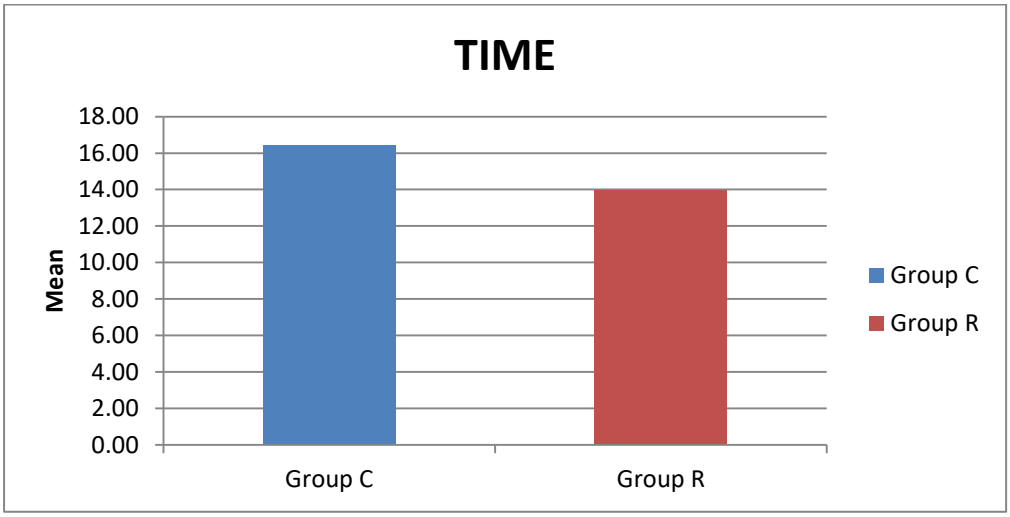

Figure 10: Distribution of patients according to mean time of insertion of I-gel® in the two groups.

Table 10: Distribution of patients according to the criteria for successful placement

		Group C		Group R		Total
		No. of cases	%	No. of cases	%	
Visible chest rise	Y	50	100%	50	100%	100
B/L equal chest auscultation	Y	50	100%	50	100%	100
Square wave capnograph	Y	50	100%	50	100%	100
OLP >10mmHg	Y	50	100%	50	100%	100
Total		50	100%	50	100%	100

The two groups were comparable in terms of parameters of successful placement of I-gel® i.e visible chest rise, bilateral equal chest auscultation, square wave capnograph and OLP >10mmHg.

Table 11: Distribution of patients according to Oral Leak Pressure in the two groups

	Group C		Group R		t	p-value
	Mean	SD	Mean	SD		
OLP (mmHg)	30.46	±3.76	32.12	±3.10	-2.409	0.018

There was a statistically significant difference in the OLP of both the groups with a p-value of 0.018. The mean OLP of Group C was 30.46 ± 3.76 mmHg and that of Group R was 32.12 ± 3.10 mmHg.

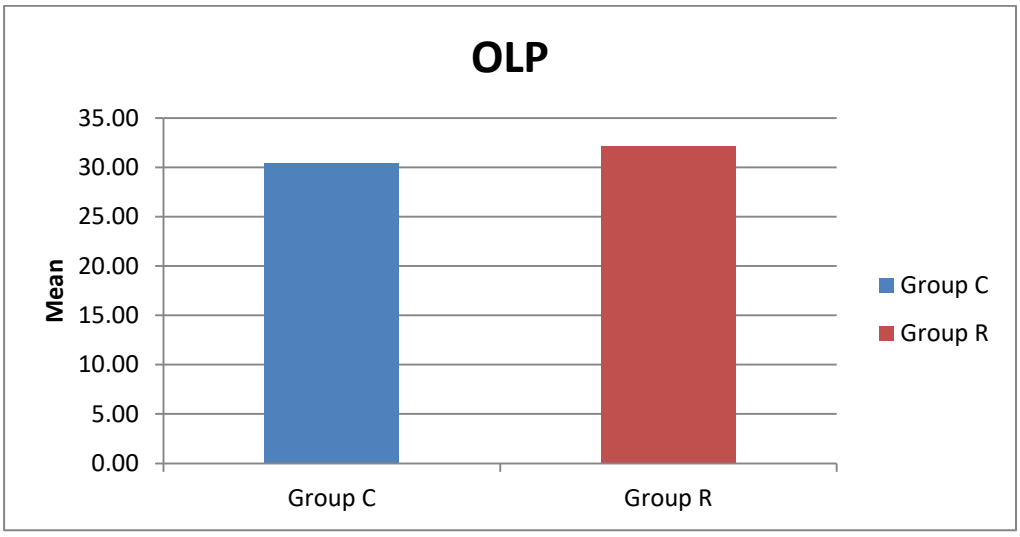

Figure 11: Distribution of patients according to Oral Leak Pressure in the two groups.

Table 12: Distribution of patients according to manipulations required for successful placement.

Manipulation	Group C		Group R		Total	Chi-square value	p-value
	No. Of cases	%	No. Of cases	%			
Withdrawal and advancement	5	10%	0	0%	5	5.263	0.022
Chin lift	3	6%	1	2%	4	1.042	0.307
Jaw thrust	0	0%	0	0%	0		
Head extension and neck flexion	2	4%	2	4%	4	0.000	1.000

Withdrawal and advancement was required in 10% of the patients in Group C while none was required in Group R, this difference was statistically significant with p-value of 0.022

Chin lift was performed in 6% patients, head extension and neck flexion in 4% and no patient required jaw thrust in Group C whereas 2% patient required chin lift, 4% required head extension and neck flexion and no patient required jaw thrust in Group R and these manipulations were statistically insignificant.

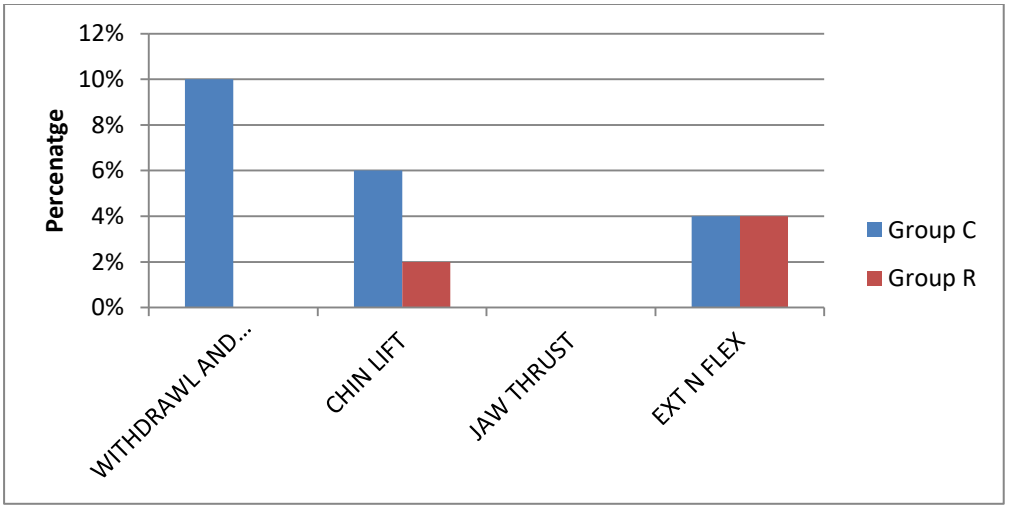

Figure 12: Distribution of patients according to manipulations required for successful placement.

Table 13: Distribution of patients according to total attempts required for successful placement

		Group C		Group R		Total	Chi-square value	p-value
		No. of cases	%	No. of cases	%			
Total attempts	1	49	98%	49	98%	98	0.000	1.000
	2	1	2%	1	2%	2		
Total		50	100%	50	100%	100		

Total number of attempts required for successful placement in both the groups were comparable.

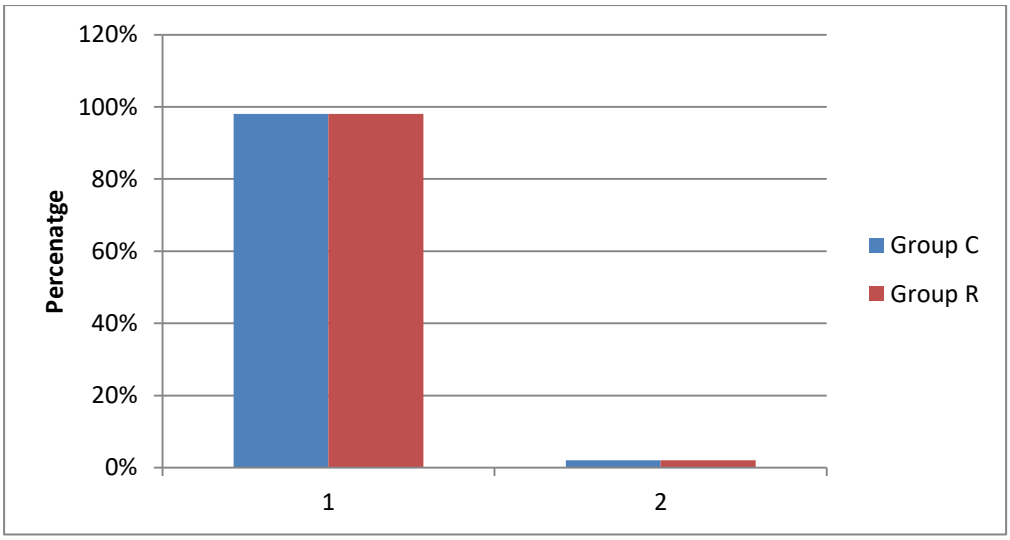

Figure 13: Distribution of patients according to total attempts required for successful placement

Table 14: Distribution of patients according to difficulty of insertion as graded by anaesthesiologist

		Group C		Group R		Total	Chi-square value	p-value
		No. of cases	%	No. of cases	%			
Difficulty of insertion	Difficult	1	2%	1	2%	2	0.769	0.681
	Easy	32	64%	36	72%	68		
	Moderate	17	34%	13	26%	30		
Total		50	100%	50	100%	100		

The difficulty of insertion as graded by the anaesthesiologist inserting the device for Group C, was easy in 64% of the patients, moderate in 34% of the patients and difficult in 2% of the patients while in Group R it was easy in 72% of the patients, moderate in 30% of the patients and difficult in 2%. The results of the two groups were comparable.

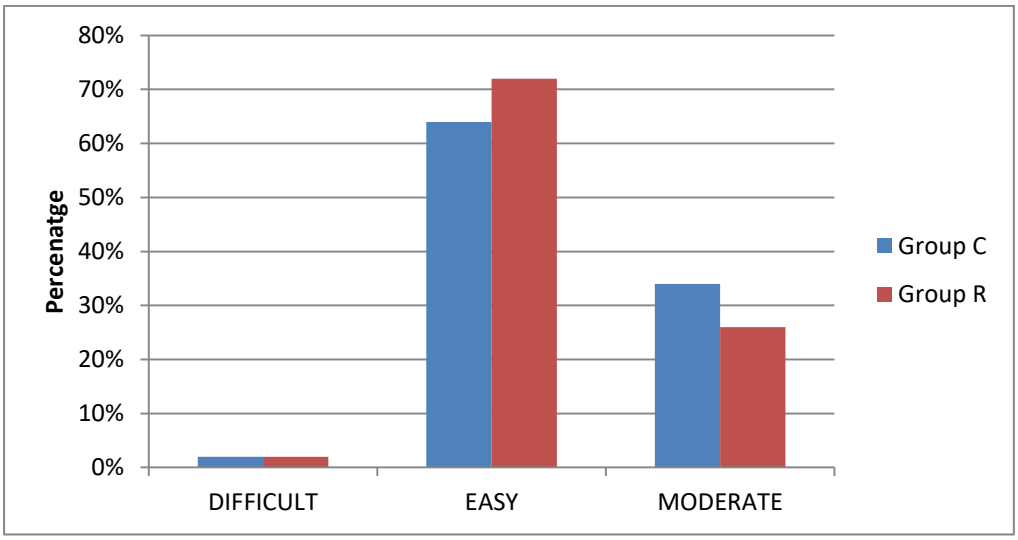

Figure 14: Distribution of patients according to difficulty of insertion as graded by anaesthesiologist

Table 15: Distribution of patients according to post I-gel® insertion complications

		Group C		Group R		Total
		No. of cases	%	No. of cases	%	
Desaturation episodes	No	50	100%	50	100%	100
Dental injury	No	50	100%	50	100%	100
Blood staining	No	50	100%	50	100%	100
Dysphagia	No	50	100%	50	100%	100
Dysphonia	No	50	100%	50	100%	100
Total		50	100%	50	100%	100

There were no intraoperative and postoperative complications related to the insertion of the device in any of the patients in both the groups.

Table 16: Distribution of patients according to Numerical rating scale in Post anaesthesia care unit.

		Group C		Group R		Total	Chi-square value	p-value
		No. of cases	%	No. of cases	%			
NRS	0	11	22%	33	66%	44	22.120	0.001
	1	33	66%	17	34%	50		
	2	6	12%	0	0%	6		
Total		50	100%	50	100%	100		

The Numerical Rating Scale of sore throat post extubation of I-gel® was compared between the two groups which showed that in Group C 22% patients did not experience any sore throat, 66% patients graded it as NRS 1 and 12% patients graded it as NRS 2 whereas in Group R 66% of the patients did not experience any post procedural sore throat, 34% patients rated it NRS 1 while no patient rated an NRS 2 in this group. These results were statistically significant with a p-value of 0.001.

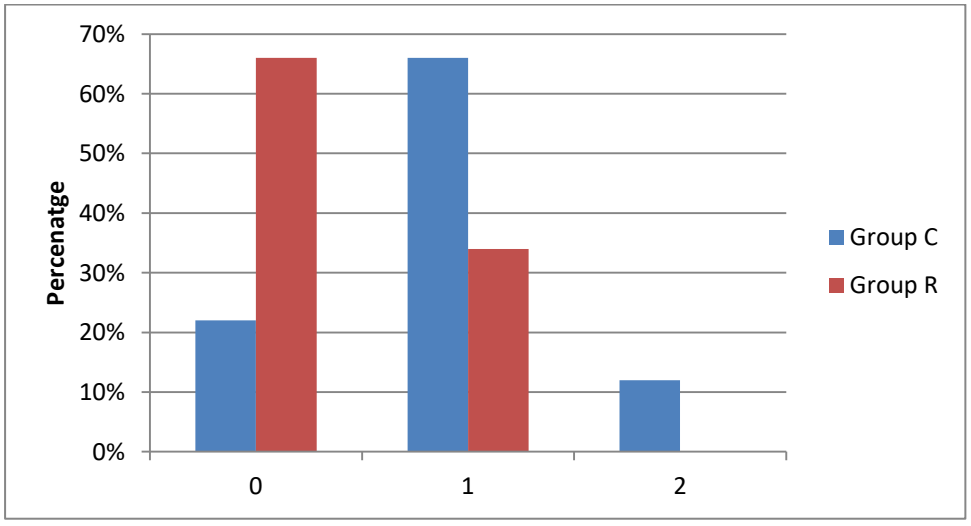

Figure 15: Distribution of patients according to Numerical rating scale in Post anaesthesia care unit.

DISCUSSION

The use of supraglottic airway devices for elective surgeries and as rescue airway has led to improvement in airway management, but it's use in obese patients is still controversial. Obese patients present with a physiological and an anatomical difficult airway. Second generation supraglottic airway devices provide effective ventilation due to better seal, have high leak pressures and also act as conduits for intubation.[3] We studied the role of I-gel® in airway management of obese patients and compared its clinical performance in terms of different techniques of insertion.

A second generation LMA I-gel® has a non-inflatable cuff which makes it easier to insert and the thermoelastic material of the cuff fits to the perilaryngeal anatomy appropriately. It has an integral bite block which is an added safety feature. Theiler et al studied I-gel® supraglottic airway in a prospective, observational study and found that obesity was not identified as a risk factor for the failure of this device. [13] Weber et al compared I-gel® and LMA-Unique in patients with mild to moderate obesity and demonstrated that I-gel® required less time for its insertion and had significantly higher leak pressure than LMA-Unique, also the leak pressure was more for moderate obesity than mild obesity. [15] I-gel® is therefore safe and effective in patients with mild to moderate obesity; hence we decided to use I-gel® in our subset of obese patients.

The mean Oral Leak Pressure of both the Groups in our study was higher when compared to studies done on non-obese population. Prabha et al compared I-gel® for general anaesthesia in obese and non-obese patients. Group O comprised of patients with BMI >30kg/m² and Group C consisted of patients with BMI 18.5-29.9 kg/m². The primary outcome of the study was OLP which is the most important factor to evaluate the performance of LMA. The mean OLP was higher in obese patients as compared to non-obese patients (28.7 vs 25.8 cmH_2O). OLP depends upon the seal between the cuff and perilaryngeal tissues. The anatomically shaped I-gel® is pliable and fits

to the perilaryngeal anatomy snugly and the thermoelastic material of the cuff expands due to the body temperature and provides a reliable seal. [19] They demonstrated that OLP is higher in obese patients as compared to non-obese patients due to the presence of excess soft tissue in oral and pharyngeal cavity and this finding was in accordance with the results of our study.

Apart from OLP the performance of I-gel® also depends on the technique of insertion as it helps to estimate the successful and appropriate placement of I-gel®. Multiple investigators have studied different techniques of insertion of LMA to elucidate a technique which could be easier and faster compared to the conventional technique. [21-23] Technique of insertion is an important aspect of successful placement of the device because successful and appropriate placement in the first attempt itself will reduce the need for multiple attempts leading to reduction in the period of apnea while securing the airway; it will also prevent the trauma caused by multiple attempts of insertion. The easier and faster technique saves time while securing the airway in obese patients which will prevent multiple episodes of desaturation.

A meta-analysis conducted by Park et al to compare standard and rotational technique for insertion of supraglottic airway devices like LMA Classic, LMA Proseal, Softseal and I-gel® reported that rotational technique provides higher first attempt and overall success rates, faster insertion and lesser number of attempts, but data was still insufficient to conclude that OLP a key parameter of successful placement was higher by rotational technique than the standard technique.[42] The first randomised controlled trial of I-gel® insertion by a non-conventional technique was published by Kim et al who studied insertion of I-gel® by standard and rotational technique. They found that tongue folding leading to impaction of I-gel® at the back of the mouth during insertion by conventional technique is the most commonly encountered difficulty. I-gel® is conventionally inserted with the concavity of the device facing the mandible and inserting it till it fits over the larynx while in rotational technique the concavity of the I-gel® faces laterally inside the oral

cavity and on reaching the oropharynx the device is rotated 90° and is further advanced till it fits over the larynx. Insertion of I-gel® using the rotational technique leads to easier placement and higher OLP than standard technique. [17]

Reverse insertion of Proseal and other SADs have been studied with their cuff collapsed, but very few studies have been done on reverse insertion of I-gel® as it has a characteristic non-inflatable cuff. In reverse insertion I-gel® is inserted with the concavity of the device facing the hard palate and rotated to 180° on reaching the oropharynx and is further advanced till it fits over the larynx. [21, 23]

Bhardwaj et al did a study to compare the three different techniques; standard, reverse and rotational techniques for insertion of LMA I-gel® in terms of insertion characteristics, first attempt and overall success rate. They found better first attempt placement and overall success rate along with higher leak pressures with reverse technique but the results were statistically insignificant. [23] In our study we also observed better placement and a significantly higher Oral Leak Pressures with reverse technique than conventional technique of I-gel® insertion (p-value 0.018). This difference could be because our subset of study population was obese and all these studies were done in non-obese patients. Current literature evidence on use of reverse technique of insertion for I-gel® in obese patients is lacking. However, by reversing this device the tongue folding is avoided and it also reduces the resistance between I-gel® and posterior pharyngeal wall. The pliable nature of its cuff and the excess perilaryngeal soft tissue in the airway of obese patients helps in pushing the I-gel® cuff more effectively leading to a better seal and higher leak pressures between the cuff of I-gel® and laryngeal inlet. This could be the reason that Oral Leak Pressures in our study were significantly higher with reverse technique.

The two groups in our study were also compared in terms of successful placement at first attempt. The results between the two groups were comparable and both the groups had high success rates of insertion at first attempt. I-gel® is used as the rescue device for oxygenation in difficult airway because it is known to have high success rate at first

attempt and it is easier to insert even by inexperienced users. Krishnappa et al studied optimal depth of anaesthesia for LMA insertion and concluded that loss of motor response to jaw thrust imitates the stretch induced stimulus required for LMA insertion and therefore can be used as a reliable indicator for insertion of LMA. [31] The depth required for insertion of LMA can be achieved by the use of induction agent alone and usually does not require the use of muscle relaxants. However, the dose of propofol for insertion of LMA should be sufficient enough to depress the airway reflexes to prevent laryngospasm, cough or hemodynamic complications. The use of muscle relaxants decrease the tone of muscles of larynx and pharynx and increases the relaxation of jaw, this facilitates the passage of the device in oral cavity and proper placement over the glottis which helps in appropriate placement of the device. [19] Nada EN in a study on efficacy of low-dose rocuronium in reducing induction dose of propofol for insertion of classic LMA ,concluded that use of muscle relaxant reduces the requirement of propofol during induction and facilitates the insertion of LMA. [29] Nasseri K studied effect of low dose atracurium on LMA insertion and compared the ease of insertion in patients receiving atracurium versus placebo (normal saline). They demonstrated that low doses of atracurium increases the jaw relaxation and facilitates LMA insertion. It also decreases the time needed for LMA insertion and post-operative sore throat. [30] Higher doses of propofol causes hemodynamic instability, so we used propofol along with opioids and low dose of atracurium to facilitate the insertion of I-gel® in our study group of patients and observed high rates of successful placement in both the groups.

The ease of insertion of I-gel® was comparable between the two techniques. The mean time of insertion in Group C was 16.42 ± 1.86 sec and in Group R was 13.98 ± 1.97 sec with a p-value of 0.001 sec which was statistically significant. The findings are consistent with studies done by Sharda et al and Bhardwaj et al; who compared insertion of I-gel® by conventional and reverse techniques in terms of time of insertion, ease and appropriate placement of the I-gel®, airway

leak pressures. They found that the reverse technique of insertion was easier and had better success rate of first attempt but the difference was not statistically significant. The time of insertion of reverse technique was significantly less than the conventional technique. In both the groups the device was placed appropriately. [21, 23]

Minimal manipulations were required in both the groups for successful placement of I-gel® in our study. Manoeuvres like chin lift, jaw thrust, extension and flexion of the neck were comparable while there was a statistically significant (p value 0.022) withdrawal and advancement manoeuvre in Group C (10%) and none in Group R. Our study is in coherence with other studies done by Kim et al and Bhardwaj et al, manipulations like jaw thrust, withdrawal and advancement were more with conventional technique of insertion but their results were comparable with reverse technique. [22, 23]

There were no postoperative complications noted in our study, like any desaturation episodes, dental injury, blood staining, dysphagia or dysphonia. This could be attributed to the performance by an experienced anaesthesiologist and the use of muscle relaxant which facitilated smooth insertion of I-gel®, thereby reducing the number of attempts, oral, pharyngeal and peri-laryngeal trauma. The postoperative sore throat was graded by Numerical Rating Scale in post anaesthesia care unit by the patient. A score of 4 or more was considered as indicator of sore throat, [36] although none of the patients in any groups had sore throat in our study but most patients graded NRS 0 in Group R while majorly graded NRS as 1 or 2 in Group C. There have been reports of lower incidence of sore throat after the surgery when LMA is inserted after injecting low dose atracurium to facilitate the LMA insertion. [30] The soft thermoelastic cuff of I-gel® does not require inflation and thus does not cause injury due to pressure of over-inflated cuff as in other LMAs. The thermoelastic material expands due to the temperature and adjusts to the shape according to the space available, hence the incidence of postoperative sore throat is less with the use of I-gel®.There have been reports of

blood staining and post operative sore throat when device was inserted by conventional technique as compared to reverse technique. [21-23]

The two groups in our study were comparable in terms of demographic data that is, gender, age, BMI, ASA grading, airway physical assessment, size of I-gel® inserted and mean duration of the surgery. There were however, more of female patients in both the groups which could be because we took more patients undergoing gynaecological procedures.

The hemodynamic parameters like heart rate, electrocardiography, arterial oxyhemoglobin saturation, end tidal carbon di-oxide remained stable throughout the procedure.

Limitations of our study were that blinding was not possible for insertion technique. We did not use fibreoptic bronchoscope to grade the view of glottis for appropriate placement of the device and relied on other clinical factors.

In conclusion, our study demonstrated that the I-gel® insertion by reverse technique requires less time for its insertion than the conventional technique. There is better airway seal, easy insertion, higher Oral Leak Pressures and fewer manipulations required with reverse technique than the conventional technique. Hence, we recommend the use of reverse technique of insertion in overweight and obese patients undergoing elective short surgical procedures under general anaesthesia.

SUMMARY AND CONCLUSION

The study was conducted in the Department of Anaesthesiology, Dayanand Medical College and Hospital, Ludhiana after getting approval from the Institutional ethics committee. We compared conventional and reverse techniques of insertion of I-gel® in overweight and obese patients.

One hundred ASA I-III adults with BMI ≥23 kg/m² and ≤40 kg/m² scheduled for elective surgeries under general anaesthesia lasting upto 120 min in supine position were studied in a prospective, randomised, interventional trial after obtaining a written informed consent. The patients were randomly allocated into two groups of 50 patients each using computer generated random numbers.

Group C: I-gel® was inserted by conventional technique with concavity facing the mandible in a pen-holding manner and inserting the device till it fits over the larynx.

Group R: I-gel® was inserted into the oral cavity with concavity of the device facing the hard palate and on reaching the oropharynx the device was rotated 180° and then further into the laryngopharynx till it fits over the larynx.

Patients were assessed for OLP, time of insertion of I-gel®, ease of insertion, manipulations required and post-operative complications if any. Results were analysed statistically.

We observed that Group R had better airway seal and required less time for its insertion as compared to Group C. Fewer manipulations were required for insertion of I-gel® in Group R than Group C. No post operative complications were noted in our study in any of the groups.

Hence we conclude that reverse technique of insertion of I-gel® have advantages over the conventional technique and can be used safely in overweight and obese patients.

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KEY TO MASTER CHART

ASA	American Society of Anaesthesiologist
BMI	Body mass index
CP	Cannot prognath teeth
D	Difficult
DBP	Diastolic blood pressure
$EtCO_2$	End tidal carbon di-oxide
ECG	Electrocardiography
E	Easy
F	Full
HR	Heart rate
MPS	Mallanpati score
M	Moderate
NIBP	Non invasive blood pressure
NRS	Numerical rating scale
OLP	Oral leak pressure
P	Partial
PACU	Post anaesthesia care unit
R	Removal
SP	Successful placement
SBP	Systolic blood pressure
SpO_2	Arterial oxyhemoglobin saturation
TMJ	Temporo-mandibular joint

S.NO	MRD	AGE (YEARS)	SEX	GROUP	DURATION OF SURGERY (MIN)	HEIGHT (CM)	WEIGHT (KG)	BMI (KG/M2)	CLASSIFICATION	ASA	STOPBANG	DENTITION	BUCK TEETH	MOUTH OPENING (CM)	THYROMENTAL DISTANCE (CM)	NECK MOVEMENT	NECK CIRCUMFERENCE (CM)	TMJ MOBILITY	UPPER LIP BITE TEST
1	871408	18	M	C	45	167	71	25.5	OVERWEIGHT	1	1	F	CP	5	>6.5	Normal	30	Normal	1
2	626160	44	M	C	40	170	75	26	OVERWEIGHT	2	3	F	NO	6	>6.5	Normal	32	Normal	2
3	872263	60	F	C	35	156	89	36.6	OBESE 2	2	6	F	CP	5	>6.5	Normal	35	Normal	2
4	546175	31	M	C	30	185	107	31.1	OBESE 2	2	4	F	CP	4.5	>6.5	Normal	41	Normal	2
5	782815	30	F	C	50	155	53	23.3	OVERWEIGHT	1	0	F	CP	6	>6.5	Normal	27	Normal	1
6	877632	49	F	R	30	162	74	28.2	OBESE 1	2	0	F	CP	5	>6.5	Normal	32	Normal	1
7	878170	40	F	C	40	150	56	24.9	OVERWEIGHT	2	0	F	CP	5.5	>6.5	Normal	29	Normal	1
8	879003	60	F	C	60	155	68	28.3	OBESE 1	2	3	P	CP	4.5	>6.5	Normal	35	Normal	2
9	880281	49	M	C	70	160	68	26.6	OBESE 1	2	3	F	CP	5	>6.5	Restricted	35	Normal	2
10	880362	27	M	C	70	168	85	30.1	OBESE 2	2	2	F	CP	4.5	>6.5	Normal	38	Normal	2
11	885090	59	F	R	45	150	59	26.2	OBESE 1	1	2	E	CP	5	>6.5	Normal	33	Normal	2
12	883483	60	F	R	30	154	68	28.7	OBESE 1	2	3	P	CP	4	>6.5	Normal	30	Normal	2
13	882057	36	F	R	50	162	70	26.7	OBESE 1	1	0	F	CP	5	>6.5	Normal	33	Normal	1
14	888157	30	F	C	50	158	88	35.3	OBESE 2	2	4	F	CP	4.5	>6.5	Restricted	38	Normal	2
15	653394	60	F	R	75	150	60	26.7	OBESE 1	2	2	P	CP	4.5	>6.5	Normal	33	Normal	2
16	586631	19	F	C	50	163	106	39.9	OBESE 2	2	4	F	CP	4.5	>6.5	Normal	42	Normal	2
17	909454	50	F	R	100	155	88	36.6	OBESE 2	2	3	F	CP	5	>6.5	Normal	39	Normal	2
18	911177	54	F	C	60	160	94	36.7	OBESE 2	2	4	P	CP	4.5	>6.5	Normal	41	Normal	2
19	895697	31	F	R	40	167	67	27.2	OBESE 1	1	0	F	CP	5	>6.5	Normal	29	Normal	2
20	937371	44	M	C	45	172	100	33.8	OBESE 2	2	4	F	CP	5	>6.5	Normal	42	Normal	3
21	939993	32	F	R	45	155	61	25.4	OBESE 1	2	0	F	CP	5.5	>6.5	Normal	34	Normal	2
22	940764	27	M	C	60	165	100	36.7	OBESE 2	2	4	F	CP	5.5	>6.5	Normal	43	Normal	2
23	941933	34	F	R	50	155	85	35.4	OBESE 2	2	3	P	CP	4.5	>6.5	Normal	40	Normal	3
24	402687	20	F	R	70	150	64	28.4	OBESE 1	1	0	F	CP	5.5	>6.5	Normal	33	Normal	1
25	612536	34	M	C	40	165	90	33.1	OBESE 2	2	3	F	CP	4	>6.5	Normal	38	Normal	2
26	939104	18	M	C	60	160	65	25.4	OVERWEIGHT	1	1	F	CP	5.5	>6.5	Normal	34	Normal	1
27	945090	34	F	R	60	157	93	37.7	OBESE 2	2	2	F	CP	4.5	>6.5	Normal	39	Normal	2
28	960274	60	F	R	80	165	90	33.1	OBESE 2	2	4	P	CP	4	>6.5	Normal	37	Normal	2
29	4642	46	F	R	40	158	80	32	OBESE 2	2	0	F	CP	4.5	>6.5	Normal	34	Normal	1
30	972187	36	F	R	25	159	75	29.7	OBESE 1	1	0	F	CP	4.5	>6.5	Normal	34	Normal	1
31	973017	28	F	C	35	155	58	28.3	OBESE 1	1	0	F	CP	5	>6.5	Normal	32	Normal	1
32	972378	29	F	R	40	155	66	27.5	OBESE 1	1	0	F	CP	5	>6.5	Normal	35	Normal	2
33	973349	60	F	C	30	154	56	23.6	OVERWEIGHT	2	2	E	CP	3.5	>6.5	Normal	30	Normal	2
34	972577	43	F	R	60	155	72	30	OBESE 2	2	1	P	CP	4	>6.5	Normal	36	Normal	2
35	973298	41	F	R	65	164	80	29.7	OBESE 1	1	1	F	CP	4	>6.5	Normal	38	Normal	2
36	279621	60	M	C	75	150	62	27.6	OBESE 1	1	2	P	CP	4.5	>6.5	Normal	32	Normal	1
37	416537	57	F	C	85	156	74	30.4	OBESE 2	3	2	F	CP	5	>6.5	Normal	35	Normal	2
38	973752	23	F	R	45	156	56	23	OVERWEIGHT	2	0	F	CP	5.5	>6.5	Normal	29	Normal	1
39	970805	50	F	R	90	158	76	30.4	OBESE 2	2	3	P	CP	4	>6.5	Normal	34	Normal	2
40	231140	39	F	R	60	157	88	35.7	OBESE 2	2	3	F	CP	4	>6.5	Normal	42	Normal	2
41	976626	34	F	R	50	165	98	36	OBESE 2	2	6	F	CP	4	>6.5	Normal	42	Normal	2
42	978230	45	F	C	30	155	65	27.1	OBESE 1	1	0	F	CP	5	>6.5	Normal	31	Normal	1
43	977399	58	F	C	45	156	76	31.2	OBESE 2	2	0	F	CP	4	>6.5	Normal	33	Normal	2
44	973124	35	M	C	75	166	92	33.4	OBESE 2	2	2	F	CP	5	>6.5	Normal	38	Normal	1
45	939010	33	F	C	100	168	90	31.9	OBESE 2	2	2	F	CP	5	>6.5	Normal	37	Normal	1
46	979956	34	F	C	40	155	60	25	OBESE 1	1	0	F	CP	5.5	>6.5	Normal	30	Normal	1
47	978984	48	F	C	80	170	90	31.1	OBESE 2	3	3	F	CP	4	>6.5	Normal	38	Normal	2
48	979763	36	F	R	90	160	67	26.2	OBESE 1	2	0	F	CP	4.5	>6.5	Normal	32	Normal	1
49	572419	50	F	R	50	158	82	32.8	OBESE 2	2	2	P	CP	4.5	>6.5	Normal	34	Normal	1
50	627182	45	F	C	30	158	70	28	OBESE 1	2	0	F	CP	5.5	>6.5	Normal	30	Normal	1
51	981086	30	F	R	45	162	72	27.4	OBESE 1	1	0	F	CP	5	>6.5	Normal	30	Normal	2
52	980664	33	F	R	70	155	72	30	OBESE 2	2	0	F	CP	5	>6.5	Normal	32	Normal	1

S.NO	MRD	MPS	ABNORMAL HEAD AND NECK ANATOMY	SIZE OF I-GEL	BASELINE HR	BASELINE ECG	BASELINE SBP	BASELINE DBP	BASELINE SPO2	BASELINE EtCO2	HR 1MIN	ECG 1MIN	SBP 1MIN	DBP 1MIN	SPO2 1MIN	EtCO2 1MIN	HR 2MIN	ECG 2MIN	SBP 2MIN	DBP 2MIN	SPO2 2MIN	EtCO2 2MIN	HR 3MIN	ECG 3MIN	SBP 3MIN
1	871408	2	No	4	80	NSR	110	60	99	32	84	NSR	100	60	99	30	84	NSR	100	60	98	30	86	NSR	110
2	626160	3	No	4	84	NSR	138	90	99	34	88	NSR	120	80	100	28	90	NSR	140	90	100	32	84	NSR	130
3	872263	4	No	4	96	NSR	166	90	97	30	96	NSR	144	70	100	28	92	NSR	130	66	100	28	90	NSR	130
4	546175	3	No	5	70	NSR	140	90	100	32	70	NSR	140	80	99	30	74	NSR	120	76	99	30	80	NSR	120
5	782815	2	No	4	100	NSR	130	60	98	34	90	NSR	120	80	98	36	100	NSR	116	72	98	28	110	ST	110
6	877632	2	No	4	78	NSR	120	70	99	30	82	NSR	112	64	99	31	80	NSR	110	60	99	32	84	NSR	110
7	878170	2	No	3	90	NSR	136	88	99	32	100	NSR	150	94	99	30	92	NSR	130	80	100	30	86	NSR	128
8	879003	4	No	4	82	NSR	136	84	98	32	84	NSR	136	90	98	28	90	NSR	130	80	99	30	90	NSR	126
9	880281	4	No	4	72	NSR	130	80	98	30	70	NSR	130	80	98	31	68	NSR	124	72	99	31	68	NSR	124
10	880362	3	No	4	88	NSR	140	80	98	34	88	NSR	140	80	99	32	90	NSR	132	84	99	32	92	NSR	130
11	885090	2	No	3	92	NSR	150	100	100	28	92	NSR	150	90	100	28	96	NSR	146	94	99	30	96	NSR	140
12	883483	2	No	4	78	NSR	166	96	98	32	84	NSR	164	90	100	32	80	NSR	154	90	99	32	70	NSR	140
13	882057	1	No	4	100	NSR	124	70	100	33	88	NSR	120	68	100	28	92	NSR	116	62	100	30	90	NSR	118
14	888157	4	No	4	100	NSR	148	100	100	27	104	ST	140	90	100	29	106	ST	130	88	100	30	100	NSR	130
15	653394	2	No	4	86	NSR	130	80	97	30	84	NSR	130	84	97	30	80	NSR	120	70	97	30	80	NSR	118
16	586631	1	No	5	70	NSR	120	70	98	30	74	NSR	130	80	98	31	74	NSR	126	72	98	32	76	NSR	120
17	909454	1	No	4	100	NSR	160	90	99	28	96	NSR	150	90	100	30	96	NSR	148	90	100	31	90	NSR	140
18	911177	3	No	5	68	NSR	140	80	99	32	70	NSR	140	80	99	30	70	NSR	136	80	100	30	76	NSR	140
19	895697	1	No	4	86	NSR	120	80	98	32	82	NSR	126	84	98	32	90	NSR	110	74	100	33	90	NSR	106
20	937371	4	No	5	100	NSR	140	80	96	30	104	ST	140	80	96	30	100	NSR	130	72	98	32	96	NSR	130
21	939993	3	No	3	76	NSR	130	70	99	30	76	NSR	120	80	99	30	70	NSR	120	70	99	30	70	NSR	110
22	940764	2	No	5	72	NSR	140	80	96	30	76	NSR	144	80	97	30	80	NSR	130	76	98	32	80	NSR	130
23	941933	3	No	4	80	NSR	120	80	100	34	84	NSR	114	64	100	29	82	NSR	116	60	100	34	82	NSR	120
24	402687	1	No	3	80	NSR	110	70	100	30	84	NSR	100	70	100	32	82	NSR	104	68	100	30	82	NSR	100
25	612536	3	No	4	90	NSR	126	84	98	30	90	NSR	130	80	99	30	94	NSR	130	80	99	31	92	NSR	120
26	939104	1	No	4	68	NSR	126	82	100	30	72	NSR	118	70	100	30	64	NSR	106	70	100	31	64	NSR	106
27	945090	3	No	5	90	NSR	110	70	100	35	92	NSR	106	66	100	35	86	NSR	102	60	100	28	86	NSR	100
28	960274	3	No	5	100	NSR	120	70	98	34	110	ST	124	80	98	28	106	ST	110	70	99	34	100	NSR	110
29	4642	2	No	4	72	NSR	126	76	97	30	76	NSR	130	70	98	30	80	NSR	120	74	98	30	86	NSR	110
30	972187	1	No	4	72	NSR	126	78	97	30	76	NSR	130	70	98	30	80	NSR	120	74	98	30	86	NSR	110
31	973017	1	No	4	86	NSR	118	86	98	30	92	NSR	124	84	99	30	90	NSR	110	72	100	30	96	NSR	106
32	972378	2	No	4	86	NSR	120	70	97	30	86	NSR	110	70	99	30	90	NSR	110	68	99	30	88	NSR	118
33	973349	3	No	4	80	NSR	120	80	98	32	84	NSR	114	80	98	32	84	NSR	110	70	100	32	80	NSR	110
34	972577	2	No	4	62	NSR	150	80	98	30	74	NSR	160	80	98	30	60	NSR	150	84	98	30	60	NSR	140
35	973298	3	No	4	100	NSR	140	80	99	33	104	ST	140	80	99	32	98	NSR	136	84	100	32	94	NSR	136
36	279621	1	No	4	72	NSR	140	90	97	30	70	NSR	140	84	99	30	66	NSR	130	70	99	30	66	NSR	130
37	416537	3	No	4	100	NSR	160	90	99	30	84	NSR	154	92	99	31	80	NSR	140	90	99	31	80	NSR	144
38	973752	1	No	3	106	ST	114	78	100	32	110	ST	120	70	100	32	110	ST	110	72	100	28	104	ST	104
39	970805	3	No	4	80	NSR	160	90	98	31	76	NSR	164	88	98	31	76	NSR	150	80	98	31	70	NSR	150
40	231140	4	No	4	85	NSR	130	80	98	34	82	NSR	130	80	98	34	82	NSR	120	80	99	28	78	NSR	120
41	976626	3	No	5	90	NSR	150	80	98	30	82	NSR	160	90	99	31	80	NSR	150	84	99	31	80	NSR	146
42	978230	2	No	4	68	NSR	128	80	99	30	64	NSR	120	80	99	30	64	NSR	120	70	99	30	60	NSR	120
43	977399	3	No	4	68	NSR	130	80	99	32	68	NSR	120	80	99	32	70	NSR	120	80	99	32	64	NSR	114
44	973124	2	No	5	78	NSR	130	80	99	34	80	NSR	140	80	99	34	80	NSR	132	74	99	34	84	NSR	126
45	939010	2	No	5	60	NSR	122	86	99	32	62	NSR	110	80	99	30	62	NSR	104	72	99	32	62	NSR	106
46	979956	1	No	4	80	NSR	126	74	98	30	80	NSR	120	80	99	31	84	NSR	116	70	100	32	84	NSR	110
47	978984	3	No	5	100	NSR	144	86	96	34	110	ST	144	90	96	34	110	ST	140	90	96	34	106	ST	136
48	979763	1	No	4	76	NSR	126	78	98	30	76	NSR	120	70	98	31	70	NSR	110	70	98	31	70	NSR	100
49	572419	2	No	4	90	NSR	140	86	98	32	90	NSR	130	80	99	32	84	NSR	126	80	99	32	80	NSR	120
50	627182	1	No	4	68	NSR	126	70	100	30	70	NSR	114	70	100	30	68	NSR	102	60	100	30	64	NSR	98
51	981086	2	No	4	90	NSR	116	74	100	32	92	NSR	112	70	100	32	92	NSR	100	60	100	32	94	NSR	102
52	980664	2	No	4	70	NSR	128	76	98	32	68	NSR	120	70	100	32	68	NSR	120	70	100	32	70	NSR	112

S.NO	MRD	DBP 3MIN	SPO2 3MIN	EtCO2 3MIN	HR SP	ECG SP	SBP SP	DBP SP	SPO2 SP	EtCO2 SP	HR R	ECG R	SBP R	DBP R	SPO2 R	EtCO2 R	HR PACU	ECG PACU	SBP PACU	DBP PACU	SPO2 PACU	EtCO2 PACU	VISIBLE CHEST RISE	B/L EQUAL AUSCULTATION	SQUARE WAVE CAPNOGRAPH	OLP
1	871408	58	98	30	84	NSR	124	50	98	31	90	NSR	130	80	99	32	68	NSR	120	60	98	32	Y	Y	Y	29
2	626160	90	100	28	100	NSR	140	100	100	34	106	ST	150	100	98	34	88	NSR	126	90	99	34	Y	Y	Y	24
3	872263	70	100	34	90	NSR	140	80	100	34	100	NSR	160	90	98	32	92	NSR	150	90	98	32	Y	Y	Y	37
4	546175	72	99	31	90	NSR	120	76	100	32	92	NSR	136	94	99	31	74	NSR	140	86	99	31	Y	Y	Y	32
5	782815	70	99	30	114	ST	108	68	100	35	100	NSR	124	70	99	34	90	NSR	120	70	99	32	Y	Y	Y	28
6	877632	62	100	30	90	NSR	106	60	100	32	94	NSR	120	80	100	31	84	NSR	110	70	100	31	Y	Y	Y	28
7	878170	80	100	31	86	NSR	120	70	100	31	90	NSR	126	72	99	31	86	NSR	130	78	100	31	Y	Y	Y	23
8	879003	80	98	30	92	NSR	120	80	99	30	96	NSR	140	90	99	28	88	NSR	140	80	99	28	Y	Y	Y	26
9	880281	70	99	31	68	NSR	118	64	99	31	74	NSR	120	80	99	30	70	NSR	120	80	99	30	Y	Y	Y	25
10	880362	80	99	32	86	NSR	126	70	99	32	88	NSR	140	90	99	32	90	NSR	140	90	99	32	Y	Y	Y	27
11	885090	86	99	30	88	NSR	118	60	99	27	106	ST	146	84	99	28	90	NSR	130	80	99	28	Y	Y	Y	28
12	883483	80	100	32	70	NSR	110	60	100	31	64	NSR	140	90	100	30	70	NSR	148	90	100	29	Y	Y	Y	27
13	882057	72	100	29	90	NSR	110	70	100	30	100	NSR	120	70	99	32	100	NSR	120	70	99	30	Y	Y	Y	28
14	888157	88	100	30	98	NSR	120	80	100	30	106	ST	140	84	100	27	100	NSR	150	90	100	27	Y	Y	Y	36
15	653394	70	97	31	84	NSR	130	80	99	30	90	NSR	140	80	97	30	84	NSR	130	70	97	30	Y	Y	Y	30
16	586631	70	98	32	86	NSR	106	64	98	33	90	NSR	130	80	98	32	90	NSR	130	70	98	32	Y	Y	Y	39
17	909454	80	100	30	94	NSR	146	90	100	30	92	NSR	150	90	100	30	90	NSR	140	90	100	30	Y	Y	Y	34
18	911177	90	100	30	86	NSR	130	90	100	30	76	NSR	136	82	99	32	78	NSR	130	80	99	32	Y	Y	Y	31
19	895697	70	100	33	90	NSR	110	70	100	34	96	NSR	130	80	99	36	88	NSR	120	80	98	32	Y	Y	Y	32
20	937371	70	99	32	90	NSR	130	80	98	32	106	ST	150	90	97	34	90	NSR	140	76	97	32	Y	Y	Y	32
21	939993	70	99	32	64	NSR	124	70	99	32	90	NSR	130	80	99	34	78	NSR	132	82	98	32	Y	Y	Y	29
22	940764	70	98	32	84	NSR	140	80	98	31	86	NSR	150	90	98	30	78	NSR	150	90	97	30	Y	Y	Y	31
23	941933	64	100	36	84	NSR	116	68	100	34	96	NSR	130	70	100	36	84	NSR	120	70	100	34	Y	Y	Y	27
24	402687	64	100	30	82	NSR	100	60	99	34	88	NSR	116	70	100	32	86	NSR	110	80	100	30	Y	Y	Y	27
25	612536	80	99	30	90	NSR	126	84	99	31	102	ST	140	80	99	32	100	NSR	140	80	99	31	Y	Y	Y	27
26	939104	74	100	31	70	NSR	110	70	100	31	80	NSR	114	72	100	30	70	NSR	114	70	100	30	Y	Y	Y	25
27	945090	60	100	35	90	NSR	110	80	100	38	90	NSR	116	84	100	36	92	NSR	118	78	100	34	Y	Y	Y	33
28	960274	70	99	34	110	ST	102	58	99	34	96	NSR	130	70	100	34	94	NSR	130	70	98	34	Y	Y	Y	32
29	4642	70	98	30	90	NSR	120	80	100	31	94	NSR	130	70	100	30	86	NSR	130	80	99	30	Y	Y	Y	32
30	972187	70	98	30	90	NSR	120	80	99	31	94	NSR	130	70	100	30	86	NSR	130	80	99	30	Y	Y	Y	30
31	973017	70	100	30	90	NSR	120	80	100	31	96	NSR	126	80	99	31	92	NSR	126	80	99	31	Y	Y	Y	26
32	972378	70	99	30	90	NSR	120	70	100	30	98	NSR	130	70	100	31	96	NSR	130	70	99	31	Y	Y	Y	28
33	973349	70	100	32	72	NSR	106	70	100	32	74	NSR	120	70	100	30	70	NSR	110	70	100	30	Y	Y	Y	30
34	972577	90	98	30	80	NSR	110	70	99	32	82	NSR	160	80	98	32	70	NSR	150	90	98	32	Y	Y	Y	35
35	973298	80	100	32	98	NSR	140	80	100	32	100	NSR	150	80	100	32	90	NSR	144	76	99	32	Y	Y	Y	35
36	279621	80	99	30	60	NSR	126	74	99	31	78	NSR	146	94	98	31	80	NSR	150	80	98	31	Y	Y	Y	32
37	416537	90	99	33	78	NSR	140	90	99	34	86	NSR	150	80	99	32	86	NSR	140	80	99	32	Y	Y	Y	32
38	973752	68	100	34	110	ST	100	60	100	35	114	ST	110	60	100	33	106	ST	120	68	100	33	Y	Y	Y	28
39	970805	80	98	31	60	NSR	140	84	99	32	68	NSR	140	80	99	32	68	NSR	150	82	98	32	Y	Y	Y	32
40	231140	80	99	32	90	NSR	126	84	99	34	90	NSR	136	86	98	34	88	NSR	132	80	98	34	Y	Y	Y	34
41	976626	84	99	31	78	NSR	144	86	99	32	90	NSR	140	80	99	31	86	NSR	144	78	99	31	Y	Y	Y	36
42	978230	70	99	34	64	NSR	100	60	100	36	64	NSR	100	60	100	34	62	NSR	110	70	100	34	Y	Y	Y	32
43	977399	76	99	32	66	NSR	118	70	99	34	72	NSR	130	72	99	34	76	NSR	120	78	99	34	Y	Y	Y	30
44	973124	70	99	34	84	NSR	126	74	99	34	88	NSR	120	70	99	34	80	NSR	120	70	99	34	Y	Y	Y	32
45	939010	70	99	32	64	NSR	110	60	99	32	60	NSR	110	70	99	32	60	NSR	110	70	99	32	Y	Y	Y	26
46	979956	70	100	32	90	NSR	112	72	100	32	90	NSR	110	70	100	32	90	NSR	120	70	99	32	Y	Y	Y	32
47	978984	90	97	34	110	ST	126	80	98	34	114	ST	140	90	98	34	108	ST	150	90	97	34	Y	Y	Y	36
48	979763	60	99	31	68	NSR	100	60	99	31	74	NSR	118	70	99	31	70	NSR	120	74	99	31	Y	Y	Y	37
49	572419	80	99	32	80	NSR	126	84	98	32	84	NSR	124	88	98	33	80	NSR	130	84	98	33	Y	Y	Y	29
50	627182	60	100	30	70	NSR	100	60	100	30	74	NSR	110	60	100	30	70	NSR	114	64	100	30	Y	Y	Y	29
51	981086	60	100	32	96	NSR	96	58	100	32	94	NSR	110	70	100	32	92	NSR	110	70	100	32	Y	Y	Y	30
52	980664	72	100	32	64	NSR	110	68	100	32	80	NSR	120	84	99	32	80	NSR	118	70	99	32	Y	Y	Y	38

S.NO	MRD	WITHDRAWAL AND ADVANCEMENT	CHIN LIFT	JAW THRUST	HEAD EXTENSION AND NECK FLEXION	CHANGE IN DEVICE	TOTAL ATTEMPTS	TIME (SEC)	DIFFICULTY OF INSERTION	DEASATURATION EPISODES	DENTAL INJURY	BLOOD STAINING	DYSPHAGIA	DYSPHONIA	NRS
1	871408	N	N	N	N	N	1	15	E	N	N	N	N	N	0
2	626160	N	N	N	N	N	1	20	M	N	N	N	N	N	1
3	872263	N	N	N	N	N	1	18	M	N	N	N	N	N	2
4	546175	Y	N	N	Y	N	1	22	M	N	N	N	N	N	1
5	782815	Y	Y	N	N	N	2	18	M	N	N	N	N	N	1
6	877632	N	N	N	N	N	1	16	E	N	N	N	N	N	0
7	878170	N	Y	N	N	N	1	15	E	N	N	N	N	N	1
8	879003	Y	N	N	N	N	1	20	M	N	N	N	N	N	2
9	880281	N	N	N	N	N	1	17	E	N	N	N	N	N	1
10	880362	N	N	N	N	N	1	18	E	N	N	N	N	N	2
11	885090	N	N	N	N	N	1	16	E	N	N	N	N	N	0
12	883483	N	N	N	N	N	1	17	E	N	N	N	N	N	1
13	882057	N	N	N	N	N	1	16	E	N	N	N	N	N	0
14	888157	Y	N	N	N	N	1	20	M	N	N	N	N	N	1
15	653394	N	N	N	N	N	1	20	M	N	N	N	N	N	1
16	586631	N	Y	N	Y	N	1	18	E	N	N	N	N	N	1
17	909454	N	Y	N	Y	N	1	20	E	N	N	N	N	N	0
18	911177	N	N	N	N	N	1	20	M	N	N	N	N	N	1
19	895697	N	N	N	N	N	1	14	E	N	N	N	N	N	0
20	937371	N	N	N	N	N	1	18	M	N	N	N	N	N	1
21	939993	N	N	N	N	N	1	15	E	N	N	N	N	N	0
22	940764	N	N	N	N	N	1	17	M	N	N	N	N	N	1
23	941933	N	N	N	Y	N	1	14	M	N	N	N	N	N	1
24	402687	N	N	N	N	N	1	14	E	N	N	N	N	N	0
25	612536	N	N	N	N	N	1	17	M	N	N	N	N	N	2
26	939104	N	N	N	N	N	1	18	E	N	N	N	N	N	0
27	945090	N	N	N	N	N	1	17	M	N	N	N	N	N	1
28	960274	N	N	N	N	N	1	16	M	N	N	N	N	N	0
29	4642	N	N	N	N	N	1	15	E	N	N	N	N	N	0
30	972187	N	N	N	N	N	1	14	E	N	N	N	N	N	0
31	973017	N	N	N	N	N	1	15	E	N	N	N	N	N	1
32	972378	N	N	N	N	N	1	13	E	N	N	N	N	N	0
33	973349	N	N	N	N	N	1	16	M	N	N	N	N	N	1
34	972577	N	N	N	N	N	1	14	M	N	N	N	N	N	1
35	973298	N	N	N	N	N	1	14	M	N	N	N	N	N	0
36	279621	N	N	N	N	N	1	16	M	N	N	N	N	N	1
37	416537	N	N	N	N	N	1	15	M	N	N	N	N	N	2
38	973752	N	N	N	N	N	1	14	E	N	N	N	N	N	0
39	970805	N	N	N	N	N	1	13	M	N	N	N	N	N	0
40	231140	N	N	N	N	N	1	12	M	N	N	N	N	N	0
41	976626	N	N	N	N	N	1	14	M	N	N	N	N	N	0
42	978230	N	N	N	N	N	1	15	E	N	N	N	N	N	1
43	977399	N	N	N	N	N	1	17	E	N	N	N	N	N	1
44	973124	N	N	N	N	N	1	16	E	N	N	N	N	N	1
45	939010	N	N	N	N	N	1	17	E	N	N	N	N	N	1
46	979956	N	N	N	N	N	1	16	E	N	N	N	N	N	1
47	978984	N	N	N	N	N	1	17	M	N	N	N	N	N	2
48	979763	N	N	N	N	N	1	12	E	N	N	N	N	N	1
49	572419	N	N	N	N	N	2	14	M	N	N	N	N	N	1
50	627182	N	N	N	N	N	1	16	E	N	N	N	N	N	0
51	981086	N	N	N	N	N	1	13	E	N	N	N	N	N	0
52	980664	N	N	N	N	N	1	12	E	N	N	N	N	N	0

S.NO	MRD	AGE (YEARS)	SEX	GROUP	DURATION OF SURGERY (MIN)	HEIGHT (CM)	WEIGHT (KG)	BMI (KG/M2)	CLASSIFICATION	ASA	STOPBANG	DENTITION	BUCK TEETH	MOUTH OPENING (CM)	THYROMENTAL DISTANCE (CM)	NECK MOVEMENT	NECK CIRCUMFERENCE (CM)	TMJ MOBILITY	UPPER LIP BITE TEST
53	980818	29	F	C	40	160	60	23.4	OVERWEIGHT	1	0	F	CP	5.5	>6.5	Normal	28	Normal	1
54	717629	23	M	R	30	168	70	24.8	OVERWEIGHT	1	1	F	CP	5.5	>6.5	Normal	29	Normal	1
55	982647	60	M	C	70	174	74	24.4	OVERWEIGHT	2	2	F	CP	5	>6.5	Normal	33	Normal	1
56	749316	60	M	R	110	168	66	23.4	OVERWEIGHT	2	2	P	CP	4.5	>6.5	Normal	34	Normal	2
57	985659	24	F	R	30	158	59	23.6	OVERWEIGHT	1	0	F	CP	5.5	>6.5	Normal	28	Normal	1
58	31460	58	F	C	40	160	98	38.3	OBESE 2	3	4	F	CP	4	>6.5	Normal	43	Normal	2
59	1007116	58	M	R	80	164	66	24.5	OVERWEIGHT	3	2	E	CP	5	>6.5	Normal	31	Normal	2
60	1006893	22	F	C	50	152	55	23.8	OVERWEIGHT	1	0	F	CP	5.5	>6.5	Normal	30	Normal	1
61	1007816	34	F	R	35	154	62	26.1	OBESE 1	1	0	F	CP	4.5	>6.5	Normal	30	Normal	1
62	8146	35	F	R	40	160	60	23.4	OVERWEIGHT	2	0	F	CP	4	>6.5	Normal	35	Normal	2
63	991147	30	F	C	40	155	65	27.1	OBESE 1	1	0	F	CP	5	>6.5	Normal	31	Normal	1
64	978128	50	M	R	120	170	78	27	OBESE 1	1	1	P	CP	4	>6.5	Normal	33	Normal	2
65	1004156	30	F	R	30	152	76	32.9	OBESE 2	2	2	P	CP	4	>6.5	Normal	36	Normal	2
66	494592	39	F	R	45	160	88	34.4	OBESE 2	2	1	F	CP	4	>6.5	Normal	37	Normal	2
67	1009155	30	F	R	25	164	67	24.9	OVERWEIGHT	1	0	F	CP	5	>6.5	Normal	33	Normal	1
68	96406	60	F	C	30	157	62	25.2	OBESE 1	1	1	P	CP	4.5	>6.5	Normal	30	Normal	2
69	997963	60	M	C	115	168	65	23	OVERWEIGHT	3	3	F	CP	4.5	>6.5	Normal	31	Normal	1
70	999620	23	M	R	75	175	80	26.1	OBESE 1	1	1	F	CP	5.5	>6.5	Normal	28	Normal	1
71	1007753	25	M	C	60	158	59	23.6	OVERWEIGHT	1	1	F	CP	5.5	>6.5	Normal	28	Normal	1
72	1008217	52	F	R	40	156	60	24.7	OVERWEIGHT	1	1	P	CP	4.5	>6.5	Normal	35	Normal	2
73	1010972	55	M	R	110	175	92	30	OBESE 2	2	4	F	CP	4	>6.5	Normal	35	Normal	2
74	1009061	60	F	C	30	150	55	24.4	OVERWEIGHT	1	1	P	CP	4	>6.5	Normal	30	Normal	2
75	1010142	34	F	R	50	164	90	33.5	OBESE 2	2	1	F	CP	4.5	>6.5	Normal	35	Normal	2
76	1011620	30	F	C	60	158	78	31.2	OBESE 2	2	1	F	CP	5	>6.5	Normal	34	Normal	1
77	1006839	30	F	C	55	174	86	28.4	OBESE 1	1	0	F	CP	5	>6.5	Normal	36	Normal	2
78	1013133	28	F	C	45	158	58	23.2	OVERWEIGHT	1	0	F	CP	5.5	>6.5	Normal	28	Normal	1
79	408250	28	F	R	30	154	55	23.2	OVERWEIGHT	1	0	F	CP	5.5	>6.5	Normal	30	Normal	1
80	1015486	27	F	R	30	154	57	24	OVERWEIGHT	1	0	F	CP	5	>6.5	Normal	31	Normal	1
81	420463	28	F	R	45	150	52	23.1	OVERWEIGHT	1	0	F	CP	5	>6.5	Normal	27	Normal	1
82	1015668	45	F	C	50	159	59	23.3	OVERWEIGHT	1	0	F	CP	5	>6.5	Normal	29	Normal	1
83	1015627	35	F	R	30	162	66	25.1	OBESE 1	1	0	F	CP	5.5	>6.5	Normal	28	Normal	1
84	1017348	36	F	C	35	164	65	24.2	OVERWEIGHT	1	0	F	CP	4.5	>6.5	Normal	30	Normal	2
85	1016087	38	F	R	30	157	60	24.3	OVERWEIGHT	1	0	F	CP	5	>6.5	Normal	29	Normal	1
86	534337	38	F	C	60	156	62	25.5	OBESE 1	2	0	F	CP	4	>6.5	Normal	32	Normal	1
87	797459	42	F	C	40	155	59	24.6	OVERWEIGHT	1	0	F	CP	5	>6.5	Normal	33	Normal	1
88	1021234	60	F	C	30	160	67	26.2	OBESE 1	1	0	F	CP	4	>6.5	Normal	32	Normal	2
89	1011488	23	M	R	40	158	69	27.6	OBESE 1	1	1	F	CP	5	>6.5	Normal	34	Normal	1
90	1022516	28	F	C	45	160	72	28.1	OBESE 1	1	0	F	CP	5	>6.5	Normal	34	Normal	2
91	922659	27	F	R	30	152	58	25.1	OBESE 1	1	0	F	CP	5	>6.5	Normal	31	Normal	1
92	1023355	26	F	C	50	158	70	28	OBESE 1	2	0	F	CP	4	>6.5	Normal	35	Normal	2
93	1022140	60	F	C	65	152	64	27.7	OBESE 1	2	2	E	CP	4.5	>6.5	Normal	30	Normal	2
94	1024775	32	F	R	35	155	64	26.6	OBESE 1	1	0	F	CP	5	>6.5	Normal	33	Normal	1
95	1024734	25	M	R	90	174	82	27.1	OBESE 1	1	1	F	CP	4.5	>6.5	Normal	32	Normal	1
96	1024751	33	F	R	50	160	70	27.3	OBESE 1	1	0	F	CP	5.5	>6.5	Normal	32	Normal	1
97	1026397	37	F	C	70	175	85	27.8	OBESE 1	1	1	F	CP	4.5	>6.5	Normal	35	Normal	2
98	1001657	20	M	C	45	178	82	25.9	OBESE 1	1	1	F	CP	5.5	>6.5	Normal	29	Normal	1
99	1026938	50	F	R	35	157	58	23.5	OVERWEIGHT	1	0	F	CP	5	>6.5	Normal	31	Normal	1
100	859265	56	F	C	40	154	74	31.2	OBESE 2	2	3	F	CP	4	>6.5	Normal	36	Normal	1

S.NO	MRD	MPS	ABNORMAL HEAD AND NECK ANATOMY	SIZE OF I-GEL	BASELINE HR	BASELINE ECG	BASELINE SBP	BASELINE DBP	BASELINE SPO2	BASELINE EtCO2	HR 1MIN	ECG 1MIN	SBP 1MIN	DBP 1MIN	SPO2 1MIN	EtCO2 1MIN	HR 2MIN	ECG 2MIN	SBP 2MIN	DBP 2MIN	SPO2 2MIN	EtCO2 2MIN	HR 3MIN	ECG 3MIN	SBP 3MIN
53	980818	1	No	3	96	NSR	106	60	100	30	100	NSR	90	60	100	30	94	NSR	90	60	100	30	94	NSR	94
54	717629	1	No	4	60	NSR	122	80	100	31	62	NSR	114	70	100	32	62	NSR	110	70	100	32	60	NSR	100
55	982647	2	No	4	70	NSR	130	80	97	30	72	NSR	126	80	99	30	74	NSR	120	70	99	30	72	NSR	120
56	749316	2	No	4	80	NSR	144	86	98	30	74	NSR	140	74	99	31	74	NSR	130	70	99	32	70	NSR	130
57	985659	1	No	3	90	NSR	124	78	100	32	86	NSR	120	70	100	32	92	NSR	114	60	100	32	92	NSR	110
58	31460	3	No	5	98	NSR	170	100	96	34	90	NSR	160	100	98	34	90	NSR	160	90	98	34	94	NSR	158
59	1007116	3	No	4	76	NSR	150	80	100	31	74	NSR	150	90	100	31	74	NSR	140	80	100	32	78	NSR	140
60	1006893	2	No	3	86	NSR	116	82	100	32	88	NSR	110	70	100	32	86	NSR	100	60	100	32	90	NSR	100
61	1007816	1	No	4	90	NSR	110	60	100	31	86	NSR	102	58	100	31	80	NSR	100	50	100	31	80	NSR	90
62	8146	2	No	3	68	NSR	126	72	99	34	72	NSR	120	70	100	34	74	NSR	108	68	100	34	70	NSR	110
63	991147	1	No	4	70	NSR	110	70	99	31	60	NSR	110	72	100	31	62	NSR	104	64	100	31	60	NSR	98
64	978128	3	No	4	62	NSR	148	92	98	34	64	NSR	144	90	99	33	60	NSR	140	80	99	33	60	NSR	140
65	1004156	3	No	4	88	NSR	150	90	96	36	90	NSR	150	90	97	28	94	NSR	140	80	98	28	94	NSR	136
66	494592	3	No	4	74	NSR	138	90	98	34	76	NSR	134	84	99	28	80	NSR	130	90	98	34	82	NSR	120
67	1009155	1	No	4	80	NSR	126	80	98	32	76	NSR	120	80	100	32	76	NSR	110	70	100	32	72	NSR	100
68	96406	2	No	4	68	NSR	150	80	98	32	66	NSR	150	80	98	33	60	NSR	130	70	98	33	60	NSR	130
69	997963	2	No	4	60	NSR	136	82	96	30	62	NSR	132	74	98	30	60	NSR	126	72	98	30	60	NSR	116
70	999620	1	No	4	60	NSR	120	70	100	31	62	NSR	116	64	100	32	62	NSR	110	64	100	32	64	NSR	110
71	1007753	1	No	3	106	ST	110	60	98	30	110	ST	100	60	99	30	100	NSR	100	60	99	30	110	ST	90
72	1008217	3	No	3	70	NSR	114	70	98	32	68	NSR	110	70	98	32	74	NSR	100	60	98	32	72	NSR	100
73	1010972	3	No	5	68	NSR	160	90	97	31	70	NSR	166	90	98	31	70	NSR	150	90	98	31	72	NSR	146
74	1009061	3	No	3	84	NSR	144	90	98	33	86	NSR	136	82	99	33	84	NSR	130	80	99	33	90	NSR	130
75	1010142	3	No	5	90	NSR	140	80	98	32	86	NSR	130	80	99	34	86	NSR	124	80	100	34	84	NSR	120
76	1011620	2	No	4	90	NSR	130	80	99	32	94	NSR	124	82	99	32	94	NSR	124	80	99	32	96	NSR	116
77	1006839	3	No	4	68	NSR	130	84	99	32	70	NSR	134	80	100	32	68	NSR	126	74	100	32	64	NSR	124
78	1013133	1	No	3	96	NSR	128	84	99	33	100	NSR	120	70	100	34	98	NSR	114	70	100	34	98	NSR	106
79	408250	2	No	3	92	NSR	120	70	100	31	100	NSR	110	70	100	31	104	ST	100	60	100	31	108	ST	100
80	1015486	2	No	3	76	NSR	116	72	99	34	78	NSR	112	70	100	28	80	NSR	114	86	100	34	80	NSR	110
81	420463	1	No	3	100	NSR	100	60	100	30	110	ST	100	60	100	32	110	ST	94	52	100	32	108	ST	90
82	1015668	2	No	3	74	NSR	128	84	100	30	70	NSR	124	84	100	30	70	NSR	120	80	100	32	66	NSR	120
83	1015627	2	No	4	90	NSR	134	82	98	32	92	NSR	130	70	99	32	88	NSR	124	64	99	32	88	NSR	120
84	1017348	2	No	4	90	NSR	130	80	98	30	92	NSR	126	84	99	32	96	NSR	112	84	99	32	96	NSR	114
85	1016087	1	No	3	68	NSR	118	80	98	34	68	NSR	118	70	99	34	64	NSR	114	74	99	33	60	NSR	110
86	534337	2	No	4	80	NSR	130	80	100	32	84	NSR	124	76	100	32	84	NSR	120	74	100	32	88	NSR	120
87	797459	2	No	3	62	NSR	120	70	98	30	64	NSR	120	70	99	31	64	NSR	116	60	99	31	68	NSR	100
88	1021234	3	No	4	64	NSR	150	90	98	32	64	NSR	140	80	98	32	62	NSR	140	80	98	32	62	NSR	142
89	1011488	1	No	4	68	NSR	130	80	99	34	64	NSR	122	84	100	28	60	NSR	116	78	100	34	60	NSR	110
90	1022516	3	No	4	90	NSR	120	70	99	31	86	NSR	120	70	100	31	84	NSR	116	60	100	31	84	NSR	110
91	922659	2	No	3	68	NSR	122	74	99	34	68	NSR	114	70	100	28	70	NSR	106	70	100	34	72	NSR	106
92	1023355	3	No	4	80	NSR	136	74	98	34	84	NSR	130	70	99	35	84	NSR	120	70	99	35	84	NSR	120
93	1022140	3	No	4	66	NSR	168	94	98	32	64	NSR	160	80	98	32	64	NSR	150	90	98	32	62	NSR	150
94	1024775	2	No	4	90	NSR	120	70	98	31	90	NSR	120	70	99	31	94	NSR	110	70	100	32	96	NSR	100
95	1024734	2	No	4	84	NSR	136	84	100	32	82	NSR	130	80	100	32	86	NSR	124	80	100	32	86	NSR	120
96	1024751	2	No	4	74	NSR	120	70	99	32	70	NSR	110	70	100	32	72	NSR	100	60	100	32	70	NSR	100
97	1026397	3	No	4	64	NSR	136	84	98	32	62	NSR	130	70	99	32	60	NSR	124	70	99	32	60	NSR	120
98	1001657	1	No	4	62	NSR	126	88	100	32	60	NSR	120	84	100	32	64	NSR	120	84	100	32	60	NSR	120
99	1026938	1	No	3	86	NSR	130	70	98	33	80	NSR	120	70	99	33	80	NSR	120	80	100	33	78	NSR	104
100	859265	3	No	4	90	NSR	150	90	98	31	94	NSR	158	92	98	31	92	NSR	146	84	98	32	90	NSR	142

S.NO	MRD	DBP 3MIN	SPO2 3MIN	EtCO2 3MIN	HR SP	ECG SP	SBP SP	DBP SP	SPO2 SP	EtCO2 SP	HR R	ECG R	SBP R	DBP R	SPO2 R	EtCO2 R	HR PACU	ECG PACU	SBP PACU	DBP PACU	SPO2 PACU	EtCO2 PACU	VISIBLE CHEST RISE	B/L EQUAL AUSCULTATION	SQUARE WAVE CAPNOGRAPH	OLP
53	980818	62	100	30	100	NSR	110	60	100	31	110	ST	116	64	100	31	108	ST	110	68	100	31	Y	Y	Y	30
54	717629	60	100	32	64	NSR	102	64	100	32	60	NSR	110	70	100	32	60	NSR	110	70	100	32	Y	Y	Y	32
55	982647	70	99	30	60	NSR	124	72	99	30	68	NSR	130	80	99	30	68	NSR	132	84	98	30	Y	Y	Y	36
56	749316	70	99	32	76	NSR	134	78	99	32	82	NSR	140	80	99	33	84	NSR	140	80	99	33	Y	Y	Y	32
57	985659	60	100	32	96	NSR	100	54	100	32	90	NSR	110	70	100	32	90	NSR	120	70	100	32	Y	Y	Y	28
58	31460	90	98	34	98	NSR	160	90	98	36	96	NSR	180	82	98	36	98	NSR	170	86	98	34	Y	Y	Y	39
59	1007116	80	100	32	80	NSR	130	80	100	32	84	NSR	148	82	100	32	84	NSR	144	84	100	32	Y	Y	Y	33
60	1006893	60	100	32	90	NSR	90	50	100	32	86	NSR	110	60	100	32	86	NSR	114	74	100	32	Y	Y	Y	34
61	1007816	50	100	31	76	NSR	90	50	100	32	84	NSR	110	60	100	32	82	NSR	104	66	100	32	Y	Y	Y	36
62	8146	60	100	34	60	NSR	112	70	100	34	72	NSR	116	78	100	34	70	NSR	120	80	100	34	Y	Y	Y	32
63	991147	58	100	31	64	NSR	90	60	100	32	78	NSR	108	64	100	32	82	NSR	110	60	100	32	Y	Y	Y	27
64	978128	80	99	34	70	NSR	130	70	99	34	72	NSR	130	70	99	34	72	NSR	134	78	99	34	Y	Y	Y	31
65	1004156	80	98	35	90	NSR	130	70	98	35	96	NSR	160	90	97	35	86	NSR	160	84	97	35	Y	Y	Y	38
66	494592	80	98	34	90	NSR	120	80	99	35	94	NSR	142	80	98	34	86	NSR	140	80	98	34	Y	Y	Y	35
67	1009155	60	100	32	70	NSR	100	60	100	32	80	NSR	110	70	99	32	84	NSR	110	70	99	32	Y	Y	Y	36
68	96406	70	98	33	70	NSR	126	80	98	33	68	NSR	140	80	98	33	72	NSR	140	80	98	33	Y	Y	Y	32
69	997963	70	99	30	64	NSR	120	70	98	30	64	NSR	130	70	98	30	62	NSR	130	70	98	30	Y	Y	Y	34
70	999620	70	100	32	64	NSR	110	60	100	32	66	NSR	118	74	100	32	66	NSR	120	80	100	32	Y	Y	Y	34
71	1007753	50	99	30	104	ST	92	54	99	30	110	ST	116	64	99	30	112	ST	120	70	99	30	Y	Y	Y	27
72	1008217	60	98	32	70	NSR	104	68	98	32	76	NSR	110	70	98	32	76	NSR	110	70	98	32	Y	Y	Y	34
73	1010972	82	98	31	60	NSR	140	76	98	31	64	NSR	150	94	98	31	70	NSR	154	90	98	31	Y	Y	Y	36
74	1009061	80	99	33	90	NSR	130	80	99	33	80	NSR	140	80	99	33	84	NSR	140	80	99	33	Y	Y	Y	32
75	1010142	80	100	34	86	NSR	120	80	100	34	90	NSR	140	80	99	32	92	NSR	140	80	99	32	Y	Y	Y	36
76	1011620	74	100	32	84	NSR	114	70	100	32	90	NSR	128	72	100	32	94	NSR	124	70	99	32	Y	Y	Y	32
77	1006839	78	100	32	60	NSR	120	70	100	32	78	NSR	140	90	100	32	78	NSR	140	80	100	32	Y	Y	Y	29
78	1013133	64	100	34	90	NSR	100	60	100	34	94	NSR	116	66	100	34	90	NSR	120	70	100	34	Y	Y	Y	27
79	408250	60	100	31	100	NSR	102	54	100	32	96	NSR	114	62	100	34	94	NSR	110	68	100	33	Y	Y	Y	32
80	1015486	60	100	34	70	NSR	110	60	100	32	78	NSR	120	70	98	32	76	NSR	118	74	98	32	Y	Y	Y	33
81	420463	50	100	33	106	ST	88	50	100	33	114	ST	106	64	100	32	110	ST	110	60	100	32	Y	Y	Y	36
82	1015668	70	100	30	60	NSR	120	80	100	31	66	NSR	116	80	100	32	70	NSR	116	74	100	32	Y	Y	Y	26
83	1015627	60	99	32	76	NSR	120	60	98	34	94	NSR	124	68	98	34	94	NSR	128	70	98	32	Y	Y	Y	34
84	1017348	70	100	33	82	NSR	110	70	100	33	90	NSR	120	70	99	32	92	NSR	120	70	99	33	Y	Y	Y	30
85	1016087	60	99	33	60	NSR	100	60	99	33	68	NSR	120	70	99	34	66	NSR	120	70	99	34	Y	Y	Y	32
86	534337	70	100	32	90	NSR	110	70	100	32	90	NSR	120	80	100	32	92	NSR	124	84	100	32	Y	Y	Y	29
87	797459	60	99	32	60	NSR	110	60	99	32	72	NSR	120	66	99	32	70	NSR	120	70	99	31	Y	Y	Y	32
88	1021234	82	98	34	60	NSR	130	84	98	34	72	NSR	160	90	98	34	70	NSR	150	80	98	32	Y	Y	Y	34
89	1011488	80	100	35	60	NSR	110	80	100	34	68	NSR	120	80	99	34	68	NSR	124	84	99	34	Y	Y	Y	35
90	1022516	60	100	32	74	NSR	100	60	100	32	80	NSR	110	66	100	32	84	NSR	118	70	100	32	Y	Y	Y	29
91	922659	64	99	34	72	NSR	100	56	99	34	74	NSR	118	60	99	34	76	NSR	120	60	99	34	Y	Y	Y	31
92	1023355	70	100	36	74	NSR	116	74	100	34	82	NSR	128	74	99	34	88	NSR	128	80	99	34	Y	Y	Y	30
93	1022140	80	98	32	60	NSR	140	80	98	32	70	NSR	156	70	98	32	72	NSR	160	80	98	32	Y	Y	Y	36
94	1024775	60	100	31	104	ST	100	60	100	32	100	NSR	130	70	99	33	100	NSR	126	72	99	31	Y	Y	Y	30
95	1024734	70	100	32	90	NSR	110	70	100	32	94	NSR	120	70	100	32	94	NSR	120	70	100	32	Y	Y	Y	29
96	1024751	60	100	32	62	NSR	100	56	100	32	80	NSR	110	80	100	32	82	NSR	116	70	100	32	Y	Y	Y	30
97	1026397	70	99	31	60	NSR	116	68	99	32	68	NSR	140	80	99	31	64	NSR	130	84	99	31	Y	Y	Y	30
98	1001657	80	100	32	60	NSR	110	70	100	31	70	NSR	120	80	100	33	72	NSR	126	82	99	33	Y	Y	Y	30
99	1026938	70	100	32	64	NSR	102	68	100	32	72	NSR	124	70	100	33	76	NSR	120	70	100	33	Y	Y	Y	32
100	859265	84	98	32	84	NSR	140	80	98	32	80	NSR	160	82	98	32	84	NSR	156	96	98	32	Y	Y	Y	29

S.NO	MRD	WITHDRAWAL AND ADVANCEMENT	CHIN LIFT	JAW THRUST	HEAD EXTENSION AND NECK FLEXION	CHANGE IN DEVICE	TOTAL ATTEMPTS	TIME (SEC)	DIFFICULTY OF INSERTION	DEASATURATION EPISODES	DENTAL INJURY	BLOOD STAINING	DYSPHAGIA	DYSPHONIA	NRS
53	980818	N	N	N	N	N	1	14	E	N	N	N	N	N	0
54	717629	N	N	N	N	N	1	11	E	N	N	N	N	N	0
55	982647	N	N	N	N	N	1	15	E	N	N	N	N	N	1
56	749316	N	N	N	N	N	1	12	E	N	N	N	N	N	0
57	985659	N	N	N	N	N	1	11	E	N	N	N	N	N	0
58	31460	Y	N	N	N	N	1	17	D	N	N	N	N	N	1
59	1007116	N	N	N	N	N	1	14	D	N	N	N	N	N	1
60	1006893	N	N	N	N	N	1	14	E	N	N	N	N	N	1
61	1007816	N	N	N	N	N	1	11	E	N	N	N	N	N	0
62	8146	N	N	N	N	N	1	14	E	N	N	N	N	N	0
63	991147	N	N	N	N	N	1	14	E	N	N	N	N	N	0
64	978128	N	N	N	N	N	1	13	E	N	N	N	N	N	1
65	1004156	N	N	N	N	N	1	15	M	N	N	N	N	N	1
66	494592	N	N	N	N	N	1	13	M	N	N	N	N	N	1
67	1009155	N	N	N	N	N	1	14	E	N	N	N	N	N	0
68	96406	N	N	N	N	N	1	16	E	N	N	N	N	N	0
69	997963	N	N	N	N	N	1	14	M	N	N	N	N	N	1
70	999620	N	N	N	N	N	1	13	E	N	N	N	N	N	0
71	1007753	N	N	N	N	N	1	14	E	N	N	N	N	N	0
72	1008217	N	N	N	N	N	1	13	E	N	N	N	N	N	0
73	1010972	N	N	N	N	N	1	12	M	N	N	N	N	N	1
74	1009061	N	N	N	N	N	1	14	E	N	N	N	N	N	1
75	1010142	N	N	N	N	N	1	11	E	N	N	N	N	N	0
76	1011620	N	N	N	N	N	1	14	E	N	N	N	N	N	1
77	1006839	N	N	N	N	N	1	17	E	N	N	N	N	N	1
78	1013133	N	N	N	N	N	1	17	E	N	N	N	N	N	1
79	408250	N	N	N	N	N	1	12	E	N	N	N	N	N	1
80	1015486	N	N	N	N	N	1	15	E	N	N	N	N	N	0
81	420463	N	N	N	N	N	1	14	E	N	N	N	N	N	1
82	1015668	N	N	N	N	N	1	14	E	N	N	N	N	N	0
83	1015627	N	N	N	N	N	1	16	E	N	N	N	N	N	0
84	1017348	N	N	N	N	N	1	16	E	N	N	N	N	N	1
85	1016087	N	N	N	N	N	1	13	E	N	N	N	N	N	0
86	534337	N	N	N	N	N	1	16	E	N	N	N	N	N	1
87	797459	N	N	N	N	N	1	15	E	N	N	N	N	N	1
88	1021234	N	N	N	N	N	1	17	M	N	N	N	N	N	1
89	1011488	N	N	N	N	N	1	14	E	N	N	N	N	N	1
90	1022516	N	N	N	N	N	1	16	E	N	N	N	N	N	1
91	922659	N	N	N	N	N	1	16	E	N	N	N	N	N	0
92	1023355	N	N	N	N	N	1	17	E	N	N	N	N	N	0
93	1022140	N	N	N	N	N	1	16	M	N	N	N	N	N	1
94	1024775	N	N	N	N	N	1	12	E	N	N	N	N	N	1
95	1024734	N	N	N	N	N	1	14	E	N	N	N	N	N	1
96	1024751	N	N	N	N	N	1	13	E	N	N	N	N	N	0
97	1026397	N	N	N	N	N	1	17	E	N	N	N	N	N	0
98	1001657	N	N	N	N	N	1	14	E	N	N	N	N	N	0
99	1026938	N	N	N	N	N	1	14	E	N	N	N	N	N	0
100	859265	N	N	N	N	N	1	16	E	N	N	N	N	N	1

Baba Farid University
of Health Sciences
Sadiq Road
Faridkot-151 203 (Pb) INDIA.
Phone : 01639-256232,256236
Tele/Fax : 01639-256235
Email : Examination@bfuhs.ac.in

No. BFUHS/2K21p TH/ 5015 Date 20/4/2021

The Principal,
DMC, Ludhiana

Subject: **Approval of Plan of Thesis.**

This is to inform you that the Faculty of Medical Sciences in its meeting held on 22.01.2021 has approved the plan of thesis of **Dr. Sonali Ahuja**, a student of your college for **MD Anaesthesiology** along with the names of Supervisor/Co-Supervisor as under:-

Topic Plan of Thesis
Comparison of conventional and reverse insertion techniques of i-gel® in overweight and obese patients

Supervisor
Dr. Kamakshi Garg
Assoc. Prof.,
Dept. of Anaesthesiology,
DMCH, Ludhiana.

Co-Supervisor
Dr. Gurpreeti Kaur
Assoc. Prof.,
Dept. of Anaesthesiology,
DMCH, Ludhiana.
Dr. Anju Grewal
Prof.,
Dept. of Anaesthesiology,
DMCH, Ludhiana.

The student has to submit the three copies of thesis (along with PDF format) , to the Controller of Examinations, BFUHS, Faridkot, at least six months before the commencement of theory examination, if he/she is otherwise eligible to take the examination. He /She must directed to attach a photocopy of this letter with the forwarding letter while submitting thesis to the University along with the letter of approval of University for change of supervisor/Co-Supervisor, change of topic,(if any).

S P Singh

Dr. S P Singh MS(Oph)
Controller of Examinations

Note :

1. ***If any discrepancy found regarding topic of thesis or Supervisor/Co-Supervisor, inform undersigned within one month after issue of this letter.***
2. *The student may submit the thesis as per the schedule already conveyed i.e for May/June examination 30th Nov of the preceding the year of examination and for Nov/Dec examinations 31st May of the year of examination.*

COMPARISON OF CONVENTIONAL AND REVERSE INSERTION TECHNIQUES OF I-GEL® IN OVERWEIGHT AND OBESE PATIENTS

THESIS PROPOSAL

FOR APPROVAL OF SUBJECT OF THESIS TO BE SUBMITTED

IN PARTIAL FULFILMENT OF THE REQUIREMENTS

FOR THE DEGREE OF

Doctor of Medicine

in

ANAESTHESIOLOGY

OF THE

BABA FARID UNIVERSITY OF HEALTH SCIENCES

FARIDKOT

NOVEMBER 2019

SONALI AHUJA

DEPARTMENT OF ANAESTHESIOLOGY
DAYANAND MEDICAL COLLEGE & HOSPITAL, LUDHIANA
LUDHIANA, PUNJAB-141001

ABSTRACT OF PLAN OF THESIS

Title	Comparison of Conventional and Reverse Insertion Techniques of I-gel® in overweight and obese patients.
For the degree of	M.D. Anaesthesiology
Name of the candidate	Sonali Ahuja
Supervisor	Dr. Kamakshi Garg, Associate Professor, Department of Anaesthesiology, DMCH, Ludhiana
Co-supervisor	Dr. Gurpreeti Kaur, Associate Professor, Department of Anaesthesiology, DMCH, Ludhiana
Co-supervisor	Dr. Anju Grewal, Professor, Department of Anaesthesiology, DMCH, Ludhiana
Institution	Dayanand Medical College and Hospital, Ludhiana
University	Baba Farid University of Health Sciences, Faridkot

Introduction: I-gel® has been used in obese patients for short to medium duration surgical procedures and has been proved to be beneficial because of it's high leak pressure. Insertion techniques have contributed to successful and appropriate placement of I-gel® in the first attempt, thereby avoiding multiple episodes of desaturation and other associated respiratory or haemodynamic complications. We hypothesize that the reverse technique of insertion would confer benefits in terms of better airway seal in obese patients in comparison to the conventional insertion technique.

Aim of Study: To compare the successful placement of I-gel® in the first attempt among two different techniques of insertion in overweight and obese patients as measured by an oral leak pressure.

Materials & methods: A prospective, randomized, interventional trial will be conducted on 100 ASA I, II and III overweight and obese patients undergoing short surgical procedures under general anaesthesia who will be divided into 2 groups. In Group C, I-gel® will be inserted with conventional technique while in Group R, I-gel® will be inserted in the reverse manner. Successful placement of I-gel®, any manipulations required for successful placement, time taken for insertion, number of attempts for successful insertion, intra-operative and post-operative complications will be studied. Data collected will be statistically analysed.

Clinical Significance: Technique of insertion can influence successful placement of I-gel® in obese patients thereby creating a safety net in terms of reduced episodes of desaturation, optimal OLP, thus establishing its use as a sole airway device in short to medium duration surgical procedures.

Keywords: Overweight, Obese, I-gel®, conventional, reverse, technique.

(Signature) Candidate	(Signature) Co-supervisor	(Signature) Co-supervisor	(Signature) Supervisor	(Signature) Principal

CERTIFICATE OF FACILITIES AVAILABLE

This is to certify that the facilities for work on the subject of thesis titled **"Comparison of Conventional and Reverse Insertion Techniques of I-gel® in overweight and obese patients"** exist in the Department of Anaesthesiology at Dayanand Medical College and Hospital, Ludhiana and will be provided to the candidate. We will see that the data being included in the thesis are genuine and is collected by the candidate herself under our supervision and guidance.

Supervisor

Dr. Kamakshi Garg
Associate Professor
Department of Anaesthesiology
DMCH, Ludhiana

Co-Supervisor

Dr. Gurpreeti Kaur
Associate Professor
Department of Anaesthesiology
DMCH, Ludhiana

Dr. Anju Grewal
Professor
Department of Anaesthesiology
DMCH, Ludhiana

Head of the Department

Dr. Sunil Katyal
Professor & Head
Department of Anaesthesiology
DMCH, Ludhiana

Place : Ludhiana
Date : 7/12/19

APPROVAL PROFORMA
BY
RESEARCH & ETHICAL COMMITTEE
DAYANAND MEDICAL COLLEGE & HOSPITAL, LUDHIANA

Name of candidate	Dr. Sonali Ahuja
Department	Anaesthesiology
Topic of Thesis	Comparison of Conventional and Reverse Insertion Techniques of I-gel® in overweight and obese patients
Likely date of appearing in PG examination	MAY-JUNE 2022
Date of enrollment	11th May,2019
Name of Head of Department	Dr. Sunil Katyal
1) Supervisor **2) Co-Supervisor**	Dr. Kamakshi Garg Dr. Gurpreeti Kaur Dr. Anju Grewal
Signature of Members of Research Committee with Stamp	**Signature of Members of Ethics Committee with Stamp**
Dr. Jaspal Singh (Professor & Head, Surgery)	Mr. A K Jindal (Member, Ethics Committee)
Dr. Dinesh Gupta (Professor & Head, Medicine)	Dr. Anu Sharma (Professor, Anatomy)
Dr. Sandeep Kaushal (Assistant Dean Academics)	Dr. Deepinder K Chhina (Professor & Head, Microbiology)
Dr. Rajoo Singh Chhina (Dean Academics)	Dr. Neena Sood (Professor & Head, Pathology)
Dr. Gurpreet S Wander (Vice Principal)	Dr. Gurpreet S Wander (Vice Principal)
	Dr. Gagandeep Singh (Secretary, Ethics Committee Professor & Head, Neurology)

Approved: Yes / No

Dr. Sandeep Puri
Chairperson
Research Committee

Chairperson
Research Committee

Approved: Yes / No

Prof. Arvind Malhotra
Chairperson
Ethics Committee

Chairperson
Ethics Committee

BABA FARID UNIVERSITY OF HEALTH SCIENCES, FARIDKOT

PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION

1	NAME OF THE CANDIDATE AND ADDRESS	Dr. Sonali Ahuja HNo. 154/25 Dr. Nagpal Gali, Ganesh Colony, Camp, Yamunanagar, Haryana- 135001
2	NAME OF THE INSTITUTE	Dayanand Medical College and Hospital, Ludhiana
3	COURSE OF STUDY AND SUBJECT	M.D. Anaesthesiology
4	DATE OF ADMISSION OF COURSE	11th May 2019
5	TITLE OF THE TOPIC	Comparison of Conventional and Reverse Insertion Techniques of I-gel® in overweight and obese patients.

6. BRIEF RESUME OF THE INTENDED WORK

6.1 NEED FOR THE STUDY

Obesity leads to a physiologically difficult airway and on many occasions an anatomically difficult airway as well. Alterations in respiratory physiology include reduced functional residual capacity, increased oxygen consumption, reduced lung volumes, higher minute ventilation, reduced chest wall compliance and increased airway resistance. [1-5] This predisposes to multiple episodes of rapid desaturation during airway management especially during laryngoscopy and endotracheal intubation. [3]

Endotracheal intubation is the preferred choice for securing the airway and for mechanical ventilation during general anaesthesia in obese patients [4]. Furthermore the difficult laryngoscopy and intubation in an obese patient results in increased haemodynamic stress response. [5-7] In addition there have been reports of higher incidence of hoarseness, sore throat, dysphagia etc due to multiple attempts at endotracheal intubation. [5-7]

As an alternative to endotracheal intubation, a second generation supraglottic airway device (SAD) has proved beneficial in obese patients because of the easy insertion coupled with higher rates of first attempt successful insertion [4, 5, 8]. This facilitates in reducing the episodes of rapid desaturation with concomitant lesser stimulation of laryngeal reflexes. Trials comparing endotracheal intubation and SAD insertion have amply demonstrated lower incidence of sore throat, dysphagia and haemodynamic changes with use of latter [5, 9]. Additionally the second generation laryngeal mask airway has been observed to be associated with higher leak pressures facilitating mechanical ventilation. [3, 8] The presence of gastric drain tube provides protection against aspiration by providing a separate channel for efflux of gastric contents. [8]

Among various second generation SAD's, I-gel® is the preferred choice because of it's pliable gel like cuff made of thermoelastic material which adjusts to the patient's anatomy and provides a better seal. [7, 8, 10] The presence of separate gastric channel diminishes the risk of regurgitation and aspiration. [7, 8]

I-gel® has been used in obese patients for short to medium duration surgical procedures and has been proved to be beneficial because of it's high leak

pressure in conjunction with easier positioning and insertion.[7] It can also be used as conduit for fibreoptic bronchoscopy and guide for intubation in case we require a definitive airway after the surgery.[8, 11]

Insertion techniques contribute to successful and appropriate placement of I-gel® in the first attempt, thereby avoiding multiple episodes of desaturation and other associated respiratory or haemodynamic complications.[10]

The standard conventional technique which entails placement of I-gel® with concavity facing the mandible in a pen-holding manner and inserting the device till it fits over the larynx, has been evaluated by multiple investigators in obese patients.[7-9] They observed successful placement at the first attempt in majority of their patients. Weber et al reported insertion difficulties more frequently when using an I-gel® in comparison to LMA Unique in their obese group of patients. These difficulties encountered in insertion can be ascribed to obstruction by the bulky tongue to the smooth passage across the oro-pharyngeal cavity.[8, 10, 11]

Reverse technique in which I-gel® is inserted into the oral cavity with concavity of the device facing the hard palate and rotated 180° on reaching the oro-pharynx and then further into the laryngo-pharynx till it fits over the larynx, has been studied by various authors in non-obese individuals.[10, 12-14] They observed higher rates of successful placement than the conventional technique in terms of success at first attempt and time taken for appearance of a square wave end-tidal carbon di-oxide waveform. They also reported better seal leading to higher leak pressures.[10, 12, 13]

We hypothesize that the reverse technique of insertion would confer benefits in terms of better airway seal in obese patients in comparison to the conventional insertion technique. Since none of the studies have compared conventional versus reverse techniques of I-gel® insertion in obese patients, we propose to comparatively evaluate both of these insertion techniques of I-gel in overweight and obese patients, in terms of successful placement at first attempt, oral leak pressures, manipulations during insertion, episodes of intra-operative desaturation and post-operative complications if any.

6.2REVIEW OF LITERATURE

Obesity is usually associated with difficult airway, difficult bag mask ventilation, difficult laryngoscopy, difficult endotracheal intubation and an added risk of aspiration. [3]

Obese patients have short thick neck, restricted neck movements and more peri-laryngeal soft tissue therefore it is difficult to get the oral, pharyngeal and laryngeal inlet in line for endotracheal intubation. Apart from the anatomically difficult airway, they also have a physiologically difficult airway which includes reduced functional residual capacity, increased oxygen consumption, reduced lung volumes higher minute ventilation, reduced chest wall compliance and increased airway resistance. [1-5] This predisposes them to multiple episodes of desaturation during airway management especially during laryngoscopy and endotracheal intubation. [3]

They usually have concomitant co-morbidities like diabetes mellitus, hypertension, obstructive sleep apnoea, chronic obstructive pulmonary disease, gastro-oesophageal reflux disease, etc. [1, 2] which further predisposes them to physiologically and anatomically difficult airway.

Endotracheal intubation is the preferred choice for securing the airway and for mechanical ventilation during general anaesthesia in obese patients [4]. Furthermore the difficult laryngoscopy and intubation in an obese patient results in increased haemodynamic stress response. [5-7] In addition there have been reports of higher incidence of hoarseness, sore throat, dysphagia etc due to multiple attempts at endotracheal intubation. [5-7]

As an alternative to endotracheal intubation, a second generation supraglottic airway device (SAD) has proved beneficial in obese patients because of the easy insertion coupled with higher rates of successful insertion at first attempt. [4, 5, 8]

Multiple investigators have compared endotracheal intubation with SAD on parameters like leak pressure, ease of insertion and urgency to secure airway. They concluded that SAD can be used as an alternative to endotracheal intubation. [4, 5, 9, 17]

Zoremba M et al, recruited 162 patients posted for short to medium duration surgeries of 40-120 minutes and compared intubation and Proseal LMA in

moderately obese adults. They included the data of 134 patients after accounting for dropouts and aimed to evaluate the influence of airway management i.e intubation versus LMA on postoperative lung volumes and arterial oxygen saturation in early post-operative period. They concluded that the use of an LMA during minor peripheral surgery confers advantages for moderately obese adults in terms of early recovery of post-operative lung functions and may be considered as an alternative to endotracheal intubation for moderately obese patients undergoing short surgeries. [4]

Cochrane systematic review comparing studies on use of Proseal LMA and Endotracheal tube (ETT) in obese patients concluded that, though PLMA takes more time to insert than ETT and a failure rate of 3-5% can be anticipated in obese patients, but once properly fitted it provides equally good ventilation as endotracheal intubation. They found significant improvement in oxygenation during and after the surgery and reduced post-operative complications like coughing, sore throat, hoarseness, etc with the use of PLMA. [5]

Uppal V et al, compared I-gel® with cuffed tracheal tube during pressure controlled ventilation (PCV) in 20 patients. They found that there was no significant difference in the leak fractions between the two groups at 15-20 cm H_2O. There was no evidence of gastric insufflations with I-ge®l at any of the pressures used during PCV. Hence I-gel® can be used as a reasonable alternative to tracheal tube during PCV with moderate airway pressures.[17]

Lai CJ et al, compared I-gel® with ETT in 40 non-obese patients undergoing laproscopic pneumoperitoneum surgeries. They evaluated the respiratory parameters in supine and trendlenberg position and found no difference in the leak fraction between I-gel® and ETT group (6.20% vs 6.38% respectively), (P=0.883). They concluded that I-gel® provides a suitable alternative to ETT when using LPT positioning. The I-gel® group produced similar leak fractions, leak volumes and airway pressure to the ETT group. In addition, the I-gel® group had significantly lower resistance and higher compliance compared with the ETT group. They proposed that the difference can be because of the lower internal diameter of I-gel® as compared to ETT. [9]

SAD can be used to secure airway in elective as well as emergency situations and are proved beneficial even when dealing with obese patients.

Murphy C et al in a review stated that airway management and oxygenation in obese patients is challenging. These challenges in oxygenation and ventilation may persist throughout the perioperative period. They suggested that newer generation double lumen supraglottic airway devices provide higher leak pressures and may be considered safe in obese patients. They can also provide a conduit for bronchoscopic intubation. Although second generation SAD are safer in obese patients but there are risks of aspiration hence caution should be exercised while using these devices in morbidly obese individuals. [3]

All the different types of LMA have been studied and compared so far. Second generation LMA have a gastric outlet to prevent gastric insufflation. Various studies have shown advantages of I-gel® over other LMA. I-gel® has a non-inflatable gel like cuff made up of thermoelastic material and a buccal stabilizer to prevent malpositioning. It fits with the patient's perilaryngeal anatomy and provides a reliable seal. [7, 9, 10] It is easier to insert and has high success rates of insertion at first attempt. It can be used as a rescue device to secure airway in emergency conditions. The size of I-gel® to be inserted is based on manufacturer's guidelines (30-60 kg - size 3, 50-90 kg - size 4, >90 kg - size 5). [7, 8, 10, 11]

In a randomised trial on comparative evaluation of ProSeal LMA (P), I-gel® (I) and Supreme LMA (S) in 84 adult patients undergoing elective surgery by Singh A et al, showed that the OLP was more with P than I and S but I-gel® was easier to insert and least time consuming also. The OLP of I-gel® increased towards the end of the surgery due to its thermoelastic hood which expands due to body temperature. [6] This high OLP is advantageous for our study as it would provide better seal and hence lesser chances of oesophageal reflux.

There are many methods to check OLP. In a study by Keller C et al, four methods were suggested for assessing airway sealing pressure with LMA in adults. Test (1) audible noise: involved detection of an audible noise by listening over the mouth. Test (2) oral capnography: involved placing a carbon di-oxide sampling line 5cm inside the mouth alongside the LMA tube and

noting when CO_2 was first seen above baseline on the monitor screen. Test (3) manometric stability: involved observation of an anaeroid manometer dial as the pressure from the breathing system increased, and noting the airway pressure at which the leak was in equilibrium with fresh gas flow. Test (4) auscultation: involved detection of an audible noise using a stethoscope placed just lateral to thyroid cartilage. They concluded that all of these tests for assessing OLP are excellent. [20]

A study by Weber U et al compared I-gel® and LMA-Unique in 50 patients in terms of leak pressure, ease of insertion, time and number of attempts of insertion in mild to moderately obese patients posted for elective short-term surgeries. They observed slightly lower scores for difficulty of insertion with LMA-Unique and statistically significant shorter insertion time with I-gel®. They observed that I-gel® can be used with higher ventilatory pressures than LMA-Unique. Hence I-gel is a safe and effective alternative supraglottic airway device in patients with mild to moderate obesity with mouth opening < 4cm. [7]

Uppal V et al, studied randomized crossover comparison between the performance of I-gel® and LMA-Unique in 39 anaesthetized, paralysed non-obese adults and found that there were no significant differences between the airway leak pressures and success rate of first time insertion of the two devices. The number of manipulations required after insertion to achieve a definitive airway was similar in both the groups. They concluded that I-gel® is a reasonable alternative to LMA-U for volume controlled ventilation during anaesthesia, also it has a lower insertion time. [18]

LMA can also be inserted without the use of muscle relaxant but in obese patients muscle relaxant helps in decreasing the tone of laryngeal and pharyngeal muscles and aid in easy and less traumatic insertion of the device. [21]

In a study by Krishnappa S. et al, to assess whether loss of motor response to jaw thrust can be a reliable clinical indicator of anaesthetic depth for LMA insertion. They used propofol in titrated doses till the loss of motor response to jaw thrust in one group and fixed dose in the other. They found that loss of

motor response to jaw thrust is reliable and favourable indicator for insertion of LMA classic. [16]

Prabha R. et al compared I-gel® for general anaesthesia in obese and non-obese patients. A total of 32 patients were studied and results showed a higher mean OLP for obese patients than non-obese. The use of muscle relaxants decreased the tone of laryngeal and pharyngeal muscles and reduced the OLP of SAD. Excess parilaryngeal tissue in obese patients may lead to better seal between the cuff of I-gel® and laryngeal inlet. They concluded that I-gel® is as effective in obese patients as in non-obese patients when used for securing the airway for surgical procedures. [8]

Nasseri K. et al studied effect of low dose atracurium on LMA insertion They found that jaw relaxation and ease of LMA insertion in the study group is significantly better than the control group (without the use of relaxant). Average time needed for insertion was also significantly lower in the study group. Haemodynamic response was similar in both groups and post-operative complications like sore throat were more in control group. They concluded that using low dose atracurium decreases the time taken for LMA insertion, it increases the jaw relaxation and facilitates the placement of LMA. [21]

Technique of insertion is an important indicator for successful placement of the device. Various techniques of insertion like conventional and reverse technique to aid for easy insertion and better success rate at first attempt have been tried by different authors. The standard conventional technique which entails placement of I-gel® with concavity facing the mandible in a pen-holding manner and inserting the device till it fits over the larynx, has been evaluated by a few investigators in obese patients. They observed successful placement at the first attempt in majority of their patients. [7-9] The reverse technique in which I-gel® is inserted into the oral cavity with concavity of the device facing the hard palate and rotated 180° on reaching the oro-pharynx and then further into the laryngo-pharynx till it fits over the larynx, has been studied by various investigators in non-obese individuals. [10, 12-14] They observed higher rates of successful placement with reverse technique than the conventional technique in terms of success at first attempt and time taken for appearance of a square wave end-tidal carbon di-oxide waveform. They

also reported better seal leading to higher leak pressures with reverse technique. [10, 12, 13]

In a study conducted by Sharda et al, reverse technique of insertion of LMA I-gel® was evaluated in 100 ASA I and II patients. They found that mean time required for I-gel® insertion in reverse technique was statistically significantly less when compared with conventional technique (17.5± 6.9 and 20.8± 5.9sec respectively). The success rate of first attempt with reverse technique was also better than conventional technique but it was statistically insignificant. Placement time was long in some patients with smaller mouth openings. The study concluded that reverse technique is associated with easier insertion and lesser placement time than that with the conventional technique. The fit of LMA was similar in both groups with the leak volumes (inspired-expired tidal volumes) being similar. [10]

Sen I. et al, in a case study of a 30 yr old woman on reverse insertion technique of I-gel® concluded that the reverse technique is easy to use, atraumatic and may be used for I-gel® insertion if first attempt by classic technique fails. [20]

Reverse technique of LMA insertion has also been studied in paediatric age group patients. Soh et al, studied the use of standard and re-inforced type of LMA in 67 paediatric patients undergoing general anaesthesia and compared them using reverse and standard technique. Fifteen seconds were allowed for each attempt. A blinded observer was asked to assess the final position of LMA using a fibreoptic bronchoscope. The success rate using standard technique was 90.3% while it was 100% using reverse technique; (p=0.06). It showed that reverse technique can be used as an acceptable alternative to the standard technique. [12]

Azad AK modified the reverse technique with triple airway maneuver for placing LMA and found that the triple airway maneuver maximized the success rate of insertion at first attempt and minimized the rate of complications when compared to that of the conventional technique. [13]

Brimacombe et al studied the insertion of LMA classic, with cuff deflated, partially inflated, fully inflated with standard technique and reverse technique of insertion. The study was done on 120 ASA I and II non-obese patients.

They found that standard technique with deflated cuff and reverse technique were better than other two techniques. [14]

Kim HC. et al, studied rotational and conventional technique of I-gel® in 184 non-obese patients and concluded that the rotational group had several advantages over the standard technique such as shorter insertion time, better airway seal and fewer post operative complications. There was least resistance by the tongue and thus easy insertion of I-gel® by rotational technique. [13]

Koo B. et al also studied the same techniques using LMA flexible and found comparable results between the two groups in terms of success rate at first attempt, insertion time, manipulations required for insertion, haemodynamic variables and complications. [15] They concluded that on comparing rotational and conventional technique it was found that the rotational technique is better than conventional in terms of less resistance by the tongue, less time taken for the insertion of the device and a better or atleast a comparable success rate at first attempt.

We hypothesize that the reverse technique of insertion would confer benefits in terms of better airway seal and fit in obese patients in comparison to the conventional insertion technique. Since none of the studies have compared conventional versus reverse techniques of I-gel® insertion in obese patients, we propose to comparatively evaluate both of these insertion techniques of I-gel in overweight and obese patients, in terms of successful placement at first attempt, oral leak pressures, manipulations during insertion, episodes of intra-operative desaturation and post-operative complications if any.

6.3 AIMS AND OBJECTIVES OF THE STUDY

To compare the successful placement of I-gel in the first attempt among two different techniques of insertion in overweight and obese patients as measured by an oral leak pressure.

7. MATERIALS AND METHODS

7.1SOURCE OF DATA

The study will be conducted in Department of Anaesthesiology, Dayanand Medical College and Hospital, Ludhiana after approval from the hospital ethics committee. A written informed consent will be obtained from all patients selected for study.

7.2 METHOD OF COLLECTION OF DATA

A prospective, randomised, interventional study will be conducted on 100 ASA I, II and III adults with BMI ≥23 kg/m² and ≤40 kg/m². Cut off's for BMI are based on Asian criteria for nutritional status. Hence we shall be including overweight at risk, Obese Class I and obese Class II patients as per this criterion in our study. [22] A total of 100 patients will be recruited in the study to account for 10% possibility of drop-outs and an equal number will be randomised using computer generated random numbers contained in sealed, sequentially numbered envelopes, which shall be opened by an independent anaesthesiologist.

Inclusion criteria - Elective surgical procedures lasting upto 120 min, surgeries in supine position, adults of both sex, BMI ≥23 kg/m² and ≤40kg/m², age ≥18yrs and ≤60yrs.

Exclusion criteria – Known or predicted difficult airway, mouth opening < 2.5 cm, surgeries in prone or lateral position, BMI <23 kg/m² and >40 kg/m², ASA IV patients, pathology of the neck or upper respiratory tract, abnormal head, airway or neck anatomy like recent radiotherapy, recent oral surgery, any oral or pharyngeal growth, presence of any significant acute or chronic lung disease, emergency surgeries, thoracic surgeries, neuro-surgeries, cardiac surgeries and airway surgeries, cervical spine injury, any mass compressing over the neck, pregnancy and refusal to participate.

Group Allocation - A written informed consent will be obtained from all the patients. Patients will be divided into 2 groups of 50 patients each.

Group (C): I-gel® will be inserted by conventional technique with concavity facing the mandible in a pen-holding manner and inserting the device till it fits over the larynx (Brain's technique). [12, 14]

Group (R): I-gel® will be inserted into the oral cavity with concavity of the device facing the hard palate and on reaching the oropharynx the device will

be rotated 180° and then further into the laryngopharynx till it fits over the larynx (like Guedel's airway).[10, 12-14]

Anaesthesia technique - All patients will be subjected to routine pre-operative assessment and standard fasting protocols.

In the operating room (OR), all patients will be positioned in ramp position and pulse oximeter, non invasive blood pressure (NIBP), end tidal CO_2 ($EtCO_2$), 5 lead electrocardiography (ECG) monitors will be attached and baseline values will be recorded from the mean of three values after positioning and settling of patient on OR table. Intravenous access will be secured and intravenous injections of midazolam 0.05 mg/kg and metoclopramide 10 mg will be administered.

After pre-oxygenating the patient with 100% oxygen for 3-5 minutes with a tight fitting appropriate size anatomical face mask, anaesthesia will be induced with intravenous injections of fentanyl 2 mcg/kg and 1% propofol 2-2.5 mg/kg titrated to loss of verbal response. Neuromuscular blockade will be achieved by intravenous injection of atracurium 0.5 mg/kg. After achieving adequate jaw relaxation i.e. loss of motor response to jaw thrust,[16, 21] airway will be secured by an appropriate size I-gel® using the technique randomly allocated to that particular patient.

I-gel® size will be selected based on patient's weight as per manufacturer's guidelines (30-60 kg - size 3, 50-90 kg - size 4, >90 kg - size 5).[7, 8, 10, 11]

The front sides and back of the I-gel cuff will be lubricated with a water based jelly before insertion.

Insertion of the airway devices will be performed by an anaesthesiologist with an experience of ≥ 100 LMA insertions and ≥ 50 I-gel® insertions.[7]

A nasogastric tube of appropriate size will be passed through the gastric tube channel in all the cases.

The lungs will be mechanically ventilated using volume controlled ventilation delivered by an anaesthesia work station (Drager Fabius Plus) set to deliver a tidal volume of 8ml/kg, respiratory rate to maintain EtCO2 between 30 and 40 mmHg, inspiratory and expiratory ratio of ,1:2 and a peak end-expiratory pressure of 5 cm of water.

The total fresh gas flow will be maintained at 1.5 L/min. Anaesthesia will be maintained by desflurane 4-6% in 50:50 Oxygen and nitrous oxide. Additional fentanyl 1mcg/kg i.v. will be given when clinically needed during anaesthesia. At the end of the procedure neuromuscular blockade will be reversed using intravenous injections of neostigmine 0.04 mg/kg and glycopyrrolate 0.001 mg/kg and I-gel® will be removed after confirming the return of spontaneous and normal pattern of ventilation and sustained head lift for atleast 5 seconds. Sustained hand-grip, leg-lift or eye opening have been demonstrated to have a low sensitivity in predicting recovery of neuromuscular function. Patients will then be shifted to post-anaesthesia care unit for observation. [22]

Observations:

PRIMARY OUTCOME

Successful placement at first attempt - Successful placement of the I-gel® will be confirmed by gently squeezing the reservoir bag and observing visible chest rise, bilateral chest auscultation, appearance of a square wave end-tidal carbon dioxide waveform, [7, 8, 10] by checking oral leak pressure (OLP) and peak airway pressure of ≥10mmHg during manual controlled ventilation. [11, 15] To perform the OLP, the fresh gas flow will be adjusted to 3L/min, and the adjustable pressure limiting valve of the circle system will be completely closed. With no peak end expiratory pressure the minimum airway pressure will be measured at which audible gas leak starts to occur as heard using a stethoscope placed just lateral to the thyroid cartilage. Airway pressures will not be allowed to exceed 40cmH_2O. [7, 8]

SECONDARY OUTCOMES

Manipulations done during insertion - Any manipulations done during insertion of the I-gel® will be noted down like gentle withdrawal with advancement of the I-gel®, chin lift, jaw thrust, head extension, neck flexion or change of size. [8, 11]

Number of attempts and Failed placement - Number of attempts needed for successful placement will be recorded. A maximum of three attempts will be allowed with each device. Any change in size of device will also be considered as an attempt. [6]

If after three attempts of I-Gel® placement, the criteria for successful placement of I-Gel® are not met with, it will be considered as failed placement. Need for the change of type of airway device will also be considered as failed placement. [8]

Insertion time of I-gel® - The insertion time will be defined as the time from picking up the device until the initiation of mechanical ventilation and appearance of square wave capnograph. [7, 8] Maximum time allowed for each attempt will be 60 sec. [11]

Difficulty of insertion - The difficulty of insertion as graded by the anaesthesiologist inserting the device which will be graded as easy=1, moderate=2, difficult=3 and impossible=4. [7]

Haemodynamic parameters – HR, ECG rhythm, NIBP, SpO_2 and $EtCO_2$ will be recorded at 1 minute intervals from starting the induction till the successful placement of the device is confirmed and then once after placement of the device, after removal of the device and after shifting the patient to post anaesthesia care unit.

Complications – Staining with blood will be observed on the I-gel® at the time of removal towards the end of the surgery. [7]

Number of episodes of desaturation i.e., SpO_2 < 90% will be noted down [7], the patients will be mask ventilated with 100% oxygen till optimal SpO_2 level is reached (95%) and this time of ventilation will not be included in effective airway time. [5]

Dental injury if any will be noted down. [5]

Patients will be followed up for 12 hours after the surgery for complaints of sore throat, dysphagia and dysphonia.

Sore throat will be rated on Numerical Rating Scale (NRS 0-10) by asking the patient verbally about the intensity of throat pain, (0- no pain, 1-3- mild pain, 4-6- moderate pain, 7-10- severe pain) during the follow up in post anaesthesia care unit. A score of more than 4 on NRS will be considered as sore throat. [15]

Statistical Analysis

Data will be described in terms of range; median (inter quartile range IQR), mean ± standard deviation (± SD), frequencies (number of cases) and relative

frequencies (percentages) as appropriate. Comparison of quantitative variables between the study groups will be done using ANOVA. For comparing categorical data, Chi square ($\chi 2$) test will be performed and Fischer exact test will be used when the expected frequency is less than 5.A probability value (p value) less than 0.05 will be considered statistically significant. All statistical calculations will be done using SPSS (Statistical Package for the Social Science) SPSS 21 version statistical program for Microsoft Windows.

Sample size calculation:

Sample size calculation was based on the data from previous study, [8] which compared OLP values in obese vs non-obese patients with the use of I-gel®. The mean OLP reported was 27.38 ± 4.38 cmH_2O in the obese group.

Hence a sample size of 50 patients in each group was proposed to detect a clinically important difference of 3 cmH_2O with a standard deviation of 5 cmH_2O in OLP. This proposed sample size was calculated with an alpha error of 0.05, a power of 80% and an estimated dropout rate of 10%.

7.3 DOES THE STUDY REQUIRE ANY INVESTIGATIONS OR INTERVENTIONS TO BE CONDUCTED ON PATIENTS OR OTHER HUMANS OR ANIMALS? IF SO, PLEASE DESCRIBE BRIEFLY.

No

7.4 HAS ETHICAL CLEARENCE BEEN OBTAINED FROM YOUR INSTITUTION IN CASE OF 7.3?

Attached here with.

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DEPARTMENT OF ANAESTHESIOLOGY

DAYANAND MEDICAL COLLEGE AND HOSPITAL, LUDHIANA

PROFORMA

Sr. Number: Group: Technique of insertion:

MRD Number: Date of surgery:

Age and Sex: Duration of surgery:

DEMOGRAPHIC DATA

Height (cm): Weight (kg): BMI (kg/m²):

Nutritional status: ASA grade: STOPBANG: __/8

COMORBIDITIES

Diabetes Mellitus ( ) Hypertension ( ) OSA ( ) COPD ( )

Any other:

AIRWAY EXAMINATION

Dentition	Partial / Full / Edentulous
Buck teeth	Can prognath mouth Can prognath teeth Cannot prognath
Mouth opening (cm)	
Thyromental distance (cm)	
Neck movement	
Neck circumference (cm)	
Temporomandibular joint mobility	
Upper lip bite test	Class I / II / III
Modified Mallampati grade	
Abnormal head, neck or airway anatomy	

SIGNATURE OF CANDIDATE SIGNATURE OF SUPERVISOR

SIZE OF I-GEL® INSERTED:

HAEMODYNAMIC AND RESPIRATORY PARAMETERS

Vitals	HR (/min)	ECG Rhythm	NIBP (mmHg)	SPO_2 (%)	$EtCO_2$ (mmHg)
Baseline					
Induction					
1 min					
2 min					
3 min					
4 min					
5 min					
Till successful placement of the device					
After successful placement of the device					
After removal of the device					
After shifting the patient to PACU					

CRITERIA FOR SUCCESSFUL PLACEMENT

Parameter	YES	NO
Visible chest rise		
Bilaterally equal chest auscultation		
Appearance of a square waveform $EtCO_2$		
Oral leak pressure >10 mmHg _____ mmHg		

MANIPULATIONS REQUIRED

	YES	NO
Gentle withdrawal and advancement		
Chin lift		
Jaw thrust		
Head extension or neck flexion		

SIGNATURE OF CANDIDATE

SIGNATURE OF SUPERVISOR

Any change in the size of device required: YES / NO

If yes, Size of the device: Attempt at which size is changed:

Total number of attempts: Total time taken for insertion:

DIFFICULTY OF INSERTION AS GRADED BY THE ANAESTHESIOLOGIST

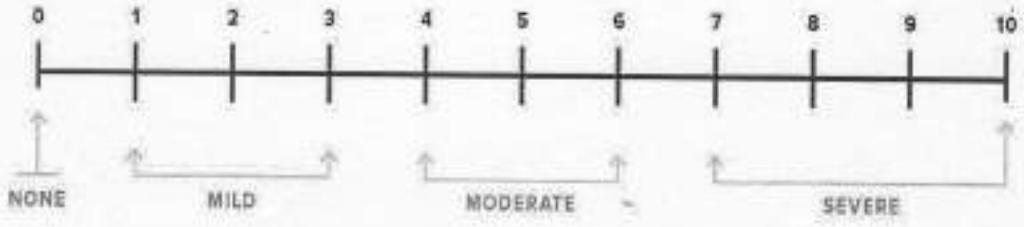
1) easy	2) moderate	3) difficult	4) impossible

COMPLICATIONS

		YES	NO
Desaturation episodes (SpO_2 less than 90%)	Number of episodes: ____		
Dental injury			
Blood staining			
Dysphagia			
Dysphonia			

SORE THROAT

0-10 NUMERIC PAIN RATING SCALE



SIGNATURE OF CANDIDATE SIGNATURE OF SUPERVISOR

INFORMED PATIENT CONSENT

Date: _____

I.....D/o, W/o, S/o.....

.....am willing to participate in the study **"Comparison of Conventional and Reverse Insertion Techniques of I-gel® in overweight and obese patients"** The procedure with its complications has been explained to me in local vernacular language. I have fully understood that no special tests and extra expenditure in any form, merely for the purpose of thesis is being carried out. I am free to opt out the study any time without assigning any reason.

.....
Signature of the Witness

Name:

.....
Signature of the patient

Signature of Supervisor

Signature of Candidate

मरीज अनुमति फार्म

तिथि _____

मैं _____ पत्नी/पुत्र/पुत्री _____

निवासी _____

इस शोधकार्य **"Comparison of Conventional and Reverse Insertion Techniques of I-gel® in overweight and obese patients"** में भाग लेने के लिए सहमत हूँ। मैं इस शोधकार्य में भाग लेने के लिए अपनी स्वेच्छा से तैयार हूँ। मैं पुष्टि करता/करती हूँ की यह स्वीकृति देने के लिए मुझे कोई आर्थिक प्रलोभन नहीं दिया गया और न ही दबाव डाला गया है। मुझे इस शोधकार्य का उद्देश्य स्पष्ट कर दिया गया है और मुझे यह विश्वास है की यह विज्ञान और मानवता के लाभ के लिए है। मुझे इस शोधकार्य में होने वाले जोखिम के बारे में समझा दिया गया है और मेरी समझ में यह जोखिम बहुत मामुली है।

मैं इस शोधकार्य में भाग लेने के सम्बन्ध में किसी भी समय अपनी अस्वीकृति व्यक्त कर सकता/सकती हूँ और मेरे अस्वीकृति व्यक्त करने का मेरे इलाज पर कोई प्रभाव नहीं पड़ेगा।

_____ _____

गवाह के हस्ताक्षर रोगी के हस्ताक्षर/अंगूठे का निशान

नाम: नाम:

_____

अन्वेषक के हस्ताक्षर

_____

विद्यार्थी के हस्ताक्षर

ਮਰੀਜ਼ ਰਜ਼ਾਮੰਦੀ ਫਾਰਮ

ਮਿਤੀ_____

ਮੈ_____ਪਤਨੀ/ਪੁੱਤਰ/ਪੁੱਤਰੀ_____

ਵਾਸੀ _____

"Comparison of Conventional and Reverse Insertion Techniques of I-gel® In overweight and obese patients" ਤੇ ਚਲ ਰਹੀ ਖੋਜ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਰਜ਼ਾਮੰਦ ਹਾਂ। ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਮੈ ਆਪਣੀ ਮਰਜ਼ੀ ਨਾਲ ਤਿਆਰ ਹਾਂ। ਮੈ ਇਹ ਦਸਣਾ ਚਾਹੁੰਦਾ ਹਾਂ/ ਚਾਹੁੰਦੀ ਹਾਂ ਕੇ ਇਹ ਰਜ਼ਾਮੰਦੀ ਦੇਣ ਵਾਸਤੇ ਮੈਨੂ ਕਿਸੇ ਵੀ ਤਰਾਂ ਦਾ ਲੋਭ-ਲਾਲਚ ਨਹੀ ਦਿੱਤਾ ਗਿਆ ਅਤੇ ਨਾ ਹੀ ਕੋਈ ਦਬਾ ਪਾਇਆ ਗਿਆ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਦਾ ਮਨੋਰਥ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਭਰੋਸਾ ਦਵਾਇਆ ਗਿਆ ਹੈ ਕੇ ਇਹ ਖੋਜ ਵਿਗਿਆਨ ਅਤੇ ਮਾਨਵਤਾ ਦੀ ਭਲਾਈ ਲਈ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਵਿਚ ਹੋਣ ਵਾਲੇ ਖਤਰੇ ਬਾਰੇ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਯਕੀਨ ਹੈ ਕੇ ਇਹ ਖਤਰਾ ਬਹੁਤ ਮਾਮੂਲੀ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਦਾ ਢੰਗ – ਤਰੀਕਾ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ।

ਮੈ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਬਾਰੇ ਆਪਣੀ ਰਜ਼ਾਮੰਦੀ ਕਿਸੇ ਵੀ ਸਮੇ ਵਾਪਸ ਲੈ ਸਕਦਾ ਹਾਂ/ ਸਕਦੀ ਹਾਂ ਅਤੇ ਮੇਰੀ ਰਜ਼ਾਮੰਦੀ ਵਾਪਸ ਲੈਣ ਦਾ ਮੇਰੇ ਇਲਾਜ ਤੇ ਕੋਈ ਅਸਰ ਨਹੀ ਹੋਵੇਗਾ।

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ਗਵਾਹ ਦੇ ਹਸਤਾਖਰ ਮਰੀਜ਼ ਦੇ ਹਸਤਾਖਰ

ਮਿਤੀ_____ ਮਿਤੀ_____

ਪਤਾ _____ ਪਤਾ _____

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ਨਿਰੀਖਕ ਦੇ ਹਸਤਾਖਰ

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ਸਿਖਿਆਰਥੀ ਦੇ ਹਸਤਾਖਰ